UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA INDIRECT PURCHASER ANTITRUST LITIGATION	No. 1:15-cv-6549 (CM) (RWL)

DECISION AND ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFF'S MOTION FOR CLASS CERTIFICATION

McMahon, C.J.:

Sergeants Benevolent Association Health & Welfare Fund ("SBA") commenced this antitrust lawsuit on behalf of itself and a putative class of similarly situated indirect purchasers of the brand and generic versions of Namenda – a drug used to treat Alzheimer's disease. Presently before the Court is Plaintiff's motion for certification of a class of third-party payors ("TPPs") that reimbursed insureds for Namenda and its generic equivalents in several states between June 1, 2012 and December 31, 2017.

SBA advances two theories of antitrust liability: (1) that Defendants' entering into several reverse-payment settlements with generic manufacturers of Namenda unlawfully delayed the market entry of generic competitors; and (2) Defendants' conduct in effectuating a "hard switch" for consumers between two versions of Namenda harmed competition.

For the reasons set forth below, I am required to analyze separately whether certification would be proper under each of the two theories of recovery proposed by SBA. *See Comcast v. Behrend*, 569 U.S. 27 (2013). I will grant the motion to certify the proposed class (with slight

modification), but only as to what I will refer to as the "pay-for-delay" theory. I am denying the motion insofar as it seeks to certify the same class (or any subclass) pursuant to the hard switch theory.

A companion *Daubert* motion seeking to exclude the opinions of one of SBA's experts is also denied.

I. BACKGROUND

This case's factual background and relevant regulatory scheme have been recounted at length in other opinions. *See New York v. Actavis, PLC* ("*Namenda I*"), No. 14-cv-7473, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014), *aff'd sub nom*. *Schneiderman ex rel. New York v. Actavis, PLC* ("*Namenda II*"), 787 F.3d 638 (2d Cir. 2015); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC* ("*Namenda III*"), No. 15-cv-7488, 2016 WL 4992690 (S.D.N.Y. Sept. 13, 2016) (denying motion to dismiss federal claims brought by direct purchasers); *In re Namenda Direct Purchaser Antitrust Litig.* ("*Namenda IV*"), No. 15-cv-7488 (CM), 2017 WL 4358244, at *1 (S.D.N.Y. May 23, 2017) (granting in part and denying in part direct purchasers' motion for collateral estoppel and partial summary judgment); *In re Namenda Direct Purchaser Antitrust Litig.* ("*Namenda V*"), 331 F. Supp.3d 152 (S.D.N.Y. 2018) (certifying class of direct purchasers); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, plc (Namenda VI)*, No. 15-cv-6549, 2018 WL 7197233 (S.D.N.Y. Dec. 26, 2018) (denying Defendants' motion to dismiss in this indirect-purchaser action); *In re Namenda Indirect Purchaser Antitrust Litig. ("Namenda VII")*, No. 15-cv-6549, 2021 WL 1000489 (S.D.N.Y. Jan. 12, 2021).

Only facts relevant to the class-certification motion are summarized below. Unless otherwise mentioned, the facts detailed are not in dispute.

A. The Product

Namenda IR (immediate release) and Namenda XR (extended release) (collectively "Namenda") are brand-name prescription drugs that contain the active ingredient memantine. Namenda is used to treat Alzheimer's disease, and has been commercially successful ever since Forest introduced Namenda IR to the U.S. market in 2003. Total annual sales of Namenda IR grew to approximately $1.5 billion by 2013, the same year that Forest launched Namenda XR. *Namenda II*, 787 F.3d at 647.

Although both versions of Namenda were patent protected, the patents had different expiration dates. Therein lies the dispute animating this lawsuit. SBA alleges that Defendants acted anticompetitively in attempting to protect Namenda's market advantage afforded by the patents, ultimately resulting in indirect purchasers paying higher prices for memantine than would otherwise have been the case but-for Defendants' conduct.

B. The Parties

Lead plaintiff Sergeants Benevolent Association Health & Welfare Fund ("SBA") is a fund that administers the prescription drug benefit plan for active and retired New York City Police Department sergeants and their dependents. It represents a class of "end payors" or indirect purchasers of Namenda, which includes – subject to some exceptions – "All Third-Party Payors who indirectly purchased, and/or paid, and/or provided reimbursement for, some or all of the price for Namenda IR 5 or 10 mg tablets, their AB-rated generic equivalents, and/or Namenda XR capsules." (ECF 489).

Third-party payors ("TPPs") are entities (besides the patient or the health care provider) that provide reimbursement for health care expenses. They include insurance companies, government payors like Medicare, and self-insured health and welfare plans run by employers. TPPs are indirect purchasers because they do not purchase drugs directly from the manufacturer

(in contrast to direct purchasers like wholesalers). Instead, they pay reimbursement for the purchases made by the individual consumers that they insure.

Defendant Forest Laboratories is a limited-liability company incorporated in Delaware that manufactures and sells branded pharmaceutical products. Forest is a wholly owned subsidiary of Defendant Actavis PLC (now known as Allergan PLC). Defendants Merz GmbH & Co. KGaA.; Merz Pharma GmbH & Co. KGaA; and Merz Pharmaceuticals GmbH (collectively "Merz") are headquartered in Germany and are also engaged in the development, production, and distribution of pharmaceutical products.

C. The Hatch-Waxman Act and Generic Competition

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, a pharmaceutical company must file a New Drug Application ("NDA") with the FDA any time it wishes to market a new brand-name drug. The NDA must provide the agency with scientific data showing that the drug is safe and effective. This generally requires conducting preclinical and clinical trials, and can take many years. *Namenda II*, 787 F.3d at 643; 21 U.S.C. § 355. Although the process is costly and time consuming, once a patented drug is approved, it enjoys a period of exclusivity on the market (generally twenty years) – effectively, a government-sanctioned monopoly. A brand-name drug's developer can recoup its investment into the drug during this exclusivity period because the drug faces no competition from generics. However, once the exclusivity period ends and generic versions of the drug enter the market, it generally results in the brand-name drug losing more than 80% to 90% of its market share within six months – a process known in the industry as going off the "patent cliff." *Namenda II*, 787 F.3d at 647.

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), Pub. L. No. 98–417, 98 Stat. 1585. Hatch-Waxman attempted to serve a dual purpose: to lower drug prices for consumers by encouraging greater generic competition

with brand-name drugs; and to incentivize innovation from branded drug manufacturers by providing for patent extensions beyond the standard 20-year patent term. *Namenda II*, 787 F.3d at 644.

To increase generic competition, Hatch-Waxman permits generic manufacturers to file an Abbreviated New Drug Application ("ANDA"), which allows them to "piggy-back" on an already-approved branded drug's NDA information to show that the generic is safe and effective. *Id.* at 644. The generic manufacturer can forgo any independent preclinical and clinic trials, but must certify that the generic has the same active ingredients as, and is "bioequivalent" to, the already-approved brand-name drug. *Ibid*; *see also* 21 U.S.C. § 355(j). Two drugs are "bioequivalent" if their "rate and extent of absorption" are not significantly different. 21 U.S.C. § 355(j)(8)(B)(i). This means that for a generic to be "bioequivalent" to a branded drug, it must deliver the same amount of the active ingredient in the same period of time. By allowing generic manufacturers to "piggy-back" their ANDAs on the studies of already-approved drugs, Hatch-Waxman reduced the development costs of lower-priced generics, speeding their introduction to the market. *Namenda II*, 787 F.3d at 644.

Apart from the federal regulatory landscape, states also heavily incentivize generic competition through drug-substitution laws – laws which either permit or require pharmacists to replace a prescribed brand-name drug with a lower-priced, "therapeutically equivalent" generic if there is no express direction from the prescribing doctor that the prescription must be filled with the brand-name drug. *Id*. at 645.

Whether a generic is "therapeutically equivalent" to the branded drug is state-dependent, but most states follow the FDA's guidance and will only substitute a generic if the FDA designates it as "AB-rated" in a publication known as the "Orange Book." *Ibid*. An AB-rated generic is one

that is both "bioequivalent" to the brand-name drug and pharmaceutically equivalent in that it has the "same active ingredient, dosage form, strength, and route of administration." *Ibid*.

However, the AB-rating requirement provides brand-name manufacturers with an opportunity to game the system by "product hopping" – developing a new version of the drug with a later patent expiration date, and then encouraging patients to switch to the new version before the original version goes off the "patent cliff." Because an AB-rating requires the generic to deliver an identical amount of the drug in the same way and over the same amount of time, a brand-name manufacturer can develop a new version of the drug with a different rate of delivery that would preclude the generic to the original version from being rated as AB-equivalent to the new version. This is what SBA alleges occurred with the two versions of Namenda, and Defendants' actions surrounding the product hop is one of SBA's two theories of liability in this case.

D. Generic Exclusivity and the Generic Settlements

To succeed on an ANDA application, a generic manufacturer must also submit a certification to the FDA describing the implications of the generic on patents held by the branded manufacturer. The relevant certification here is the "Paragraph IV" route, so named after 21 U.S.C. § 355(j)(2)(A)(vii)(IV). In a Paragraph IV certification, the generic manufacturer states that any relevant patent held by the brand-name manufacturer "is invalid or will not be infringed by the manufacture, use, or sale" of the generic. *FTC v. Actavis, Inc.*, 570 U.S. 136, 143 (2013) (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). Submitting an ANDA under Paragraph IV exposes the applicant to patent litigation. A branded manufacturer has 45 days after the submission to initiate a patent-infringement action against the ANDA applicant. If the branded manufacturer files a lawsuit, the FDA "must withhold approving the generic, usually for a 30-month period, while the parties litigate patent validity (or infringement) in court." *Ibid.*; *see also* 21 U.S.C. § 355(j)(5)(B)(iii).

Hatch-Waxman provides incentives for generic manufacturers who incur the risk of patent litigation. The generic manufacturers that first file a Paragraph IV certification (as many "first" certifications are submitted on the same day) receive a 180-day exclusive marketing period for that generic. No other generic manufacturer can market their drug during this period. "If the first-to-file generic manufacturer can overcome any patent obstacle and bring the generic to market, this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars.'" *Actavis*, 570 at 144 (citation omitted).

Like any lawsuit, the parties can decide to settle the patent-infringement litigation arising out of the ANDA. However, in such a scenario, it is usually the plaintiff (the brand-name manufacturer and patent holder) that pays to settle the case against the defendant (the generic manufacturer and alleged infringer). Thus, these settlements are called "reverse payments" or "reverse settlements." Because these payments tend to preclude, rather than encourage, market entry of generic competitors, "there is reason for concern that settlements taking this form tend to have significant adverse effects on competition." *Id*. at 148. For this reason, the Supreme Court has held that reverse payments are not immune from antitrust scrutiny. *Id*. at 141. Defendants' reverse settlements to several generic manufacturers form SBA's second theory of liability.

E. Factual History and Anticompetitive Allegations

In June 2000, Merz provided Forest with an exclusive license to U.S. Patent No. 5,061,703 (the "'703 Patent"), which gave Forest the right to market a memantine hydrochloride-based drug used to treat moderate to severe Alzheimer's disease. Forest developed Namenda IR and began marketing it in the U.S. following FDA approval in late 2003. *Namenda II*, 787 F.3d at 647. Namenda IR's exclusivity period based on the '703 Patent was originally set to expire on April 11, 2010, but in March of 2009, Forest succeeded in obtaining a five-year extension to the expiration date to April 11, 2015. Forest succeeded in later applying for another six-month extension, such

that the final expiration date of the patent was October 11, 2015. *Namenda IV*, 2017 WL 4358244, at *6.

Starting in October 2007, at least fourteen generic manufacturers – some of whom were defendants in this litigation and have since settled – submitted ANDAs with the FDA in preparation to enter the market. These ANDAs provided Paragraph IV certifications, notifying Forest of their view that the '703 Patent was either invalid or was not infringed by the generic manufacturers' versions of their memantine product. (Second Amended Complaint at ¶ 72). Forest commenced litigation against these manufacturers in January 2008, thus triggering the automatic 30-month stay under Hatch-Waxman, during which the validity of the '703 Patent was to be litigated. (*Id.* at ¶ 74).

Beginning in early 2010, several of the generic manufacturers began receiving word that their ANDAs were ready for approval following the expiration of the 30-month stay. (*Id.* at ¶¶ 85-86). Thus, generic versions of Namenda IR could have theoretically entered the market as early as mid-2010. This did not occur, however, because Forest entered into several reverse payment settlements with the generic manufacturers such that the manufacturers agreed not launch their generic versions of Namenda IR until after July 11, 2015. (*Id.* at ¶ 79). SBA alleges that these reverse payments were anticompetitive – effectively, a "pay-for-delay" scheme designed to limit generic availability.

In the interim, the FDA approved a second memantine-based drug developed by Forest in June 2010: Namenda XR. Namenda IR and Namenda XR have the same active ingredient and the same therapeutic effect, but unlike IR, which must be taken twice daily, XR needs to only be taken once a day. Yet, this difference meant that the two drugs were not bioequivalent, meaning that generics to IR would not be rated as AB-equivalent to XR. Thus, generic IR would not be

automatically dispensed pursuant to states' drug-substitution laws if XR were prescribed. Forest launched Namenda XR in 2013.

SBA claims that – anticipating the decrease in Namenda IR's market share after generic launch – Forest attempted to implement a "soft switch" between the two versions of Namenda to increase use of XR before IR fell off the patent cliff. Thus, after Forest began marketing XR in 2013, *Namenda II*, 787 F.3d at 647, it stopped advertising IR. *Namenda III*, 2016 WL 4992690, at *5. It also reduced the price of XR and encouraged prescribers to switch their patients to the once-daily version, all in an effort to encourage consumers to voluntarily switch between the two versions.

However, according to SBA, Forest decided that these efforts at a "soft switch" were unsuccessful, because by 2014 its internal projections estimated that only 30% of Namenda IR consumers would end up switching to XR before generic entry. *Namenda III*, 2016 WL 4992690, at *5. On February 14, 2014, Forest announced an intention to completely withdraw Namenda IR from the market on August 15, 2014, while keeping Namenda XR on the market. SBA alleges that the actions Defendants took surrounding this announcement represented an anticompetitive "hard switch" designed to force consumers to switch to Namenda XR without the option of remaining on the original version.

F. History of Litigation

The present litigation is the latest of several lawsuits filed against the manufacturers of Namenda and its generic counterparts. In 2014, after Forest announced its plan to discontinue Namenda IR, the State of New York sued Forest and Actavis to enjoin them from doing so, arguing that the "hard switch" was anticompetitive. *Namenda I*, 2014 WL 7015198, at * 1. The Honorable Judge Robert Sweet granted a preliminary injunction, and that ruling was affirmed on appeal. *Namenda II*, 787 F.3d at 663.

In August 2015, SBA filed the instant lawsuit, and in September 2015, direct purchasers of Namenda filed a similar lawsuit. (*See* Case No. 15-cv-7488 (CM)(RWL)). Both sets of plaintiffs alleged that Defendants' actions in effectuating the hard switch and in entering into the reverse-payment settlements forced them to pay supracompetitive prices for memantine. In contrast to the direct purchasers, who brought their claims under the federal Sherman Act, the indirect purchasers in this lawsuit bring their claims under state antitrust and consumer-protection laws. In total, SBA's operative Second Amended Complaint alleges claims arising under the antitrust laws of 24 states, and the District of Columbia. They also bring claims under the consumer-protection laws of 14 states. (ECF 326).

In September 2016, this Court denied the Defendants' consolidated motions to dismiss. *Namenda III*, 2016 WL 4992690, at * 1. The Court then stayed the indirect purchasers' litigation until a resolution of the federal claims from the direct purchasers' lawsuit. That litigation ultimately settled on the eve of trial. Following that, several of the generic defendants in this suit also settled. The only Defendants remaining in this litigation are thus those affiliated with the brand-name manufacturers and originators of Namenda – Forest and Actavis and their German counterpart, Merz.

The main motion for consideration before the Court currently is SBA's motion for class certification.

It seeks to certify the following class:

> All Third-Party Payors who indirectly purchased, and/or paid, and/or provided reimbursement for, some or all of the purchase price for branded Namenda IR 5 or 10 mg tablets, their AB-rated generic equivalents, and/or Namenda XR capsules, other than for resale, in Alabama, Arizona, California, D.C., Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island (for purchases after July 15, 2013), South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin, for

> consumption by themselves, or their members, employees, insureds, participants, or beneficiaries, from June 1, 2012 through December 31, 2017.
>
> Excluded from the proposed Class are: (a) Defendants and Defendants' parents, subsidiaries and affiliates; (b) fully-insured health care plans (i.e., health plans that purchased insurance from another third-party payor covering 100% of the insureds' prescription drug benefits on behalf of the Plan's members and beneficiaries); (c) all federal or state governmental entities, excluding cities, towns or municipalities with self-funded prescription drug plans; and (d) Pharmacy Benefit Managers ("PBMs"). (ECF 489, pg. 2).

SBA's initial class definition included "All *persons* or entities who indirectly purchased" or reimbursed for Namenda or its generics in the requisite states during the class period. (ECF 444). However, SBA amended the proposed class when it filed its reply in support of certification. The class is now smaller, limited only to TPP entities. Defendants do not contest that SBA's amending of the proposed class was prejudicial in any way. They maintain that the new class definition does not cure any of the inherent problems that Defendants highlighted in its original opposition to certification, and that their arguments against certification apply with equal force to the narrower definition. (ECF 528).

Defendants have also filed a *Daubert* motion to exclude the opinions of SBA's expert Dr. William Vogt, who offers a report detailing his opinions on the level of damages attributable to each of SBA's theories of antitrust liability. (ECF 551). Defendants filed this motion as part of the summary judgement proceedings, but I will consider it in this opinion since SBA also offers Dr. Vogt's report to support certification.

II. LEGAL STANDARDS

A. Rule 702 and the *Daubert* Standard

Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based

> on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

The Second Circuit has focused the Rule 702 "gatekeeping" inquiry into three distinct determinations: (1) that the witness is "qualified" to opine as an expert as to the particular matter; (2) "that the opinion is based upon reliable data and methodology"; and (3) that the testimony will "assist the trier of fact." *Nimely v. City of New York*, 414 F.3d 381, 397 (2d Cir. 2005).

"Although Rule 702 sets forth specific criteria for the district court's consideration, the *Daubert* inquiry is fluid and will necessarily vary from case to case." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002). The goal "is to ensure the reliability and relevancy of expert testimony," but the court has "considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). Although courts must not accept the mere *ipse dixit* of the expert, and "may conclude that there is simply too great an analytical gap between the data and the opinion proffered," *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997), they ultimately enjoy "broad latitude to determine" the reliability and admissibility of expert testimony. *Kumho Tire*, 526 U.S. at 153.

Although neither the Supreme Court nor the Second Circuit has definitively held that a *Daubert* inquiry is necessary to evaluate expert opinions offered in support of class certification, "the heavy weight of authority militat[es] towards a *Daubert* inquiry at class certification." *Namenda VII*, 2021 WL 100489, at *8 (discussing cases).

B. Rule 23 and Class Certification

Rule 23 of the Federal Rules of Civil Procedure provides the legal framework for class certification. A class may be certified only if:

> (1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a). Commonly expressed, these are the requirements of numerosity, commonality, typicality, and adequacy of representation. *See, e.g., In re LIBOR-Based Fin. Instruments Antitrust Litigation*, 299 F. Supp.3d 430, 460 (S.D.N.Y. 2018). The absence of any one of these four factors renders the class uncertifiable. *See Sykes v. Mel S. Harris and Assocs. LLC*, 780 F.3d 70, 80 (2d Cir. 2015).

In addition to the four factors expressly outlined in 23(a), the Second Circuit also requires that the proposed class be ascertainable – that "it is defined using objective criteria that establish a membership with definite boundaries." *In re Petrobras Secs.*, 862 F.3d 250, 257 (2d Cir. 2017). Satisfying this implied requirement means that a class must be bounded such that a court can determine – through "objective criteria" – whether an individual or entity is a member, and is defined in such a way that avoids a need for "a mini-hearing on the merits of each case." *Id.* at 264; *see also Brecher v. Republic of Argentina*, 806 F.3d 22, 24 (2d Cir. 2015). Ascertainability is a "modest threshold" and "will only preclude certification if a proposed class definition is indeterminate in some fundamental way." *In re Petrobras*, 862 F.3d 250 at 269.

Satisfying all four Rule 23(a) prerequisites and the ascertainability requirement does not end the analysis. Plaintiffs must also establish at least one of the three requirements listed under Rule 23(b). *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 345 (2011). Here, SBA seeks class certification under 23(b)(3), which permits a claim for class-wide damages if (1) "questions of law or fact common to class members predominate over any questions affecting only individual members" and "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed R. Civ. P. 23(b)(3). These two factors are referred to as the

predominance and superiority requirements, and both must be satisfied. *See, e.g.*, *Sykes*, 780 F.3d at 82 (referring to the Rule 23(b)(3) analysis as a "disjunctive inquiry").

Ultimately, the requirements of Rule 23 are to be construed liberally, in favor of class certification, and "the Second Circuit's general preference is for granting rather than denying class certification." *Espinoza v. 953 Assocs. LLC*, 280 F.R.D. 113, 124 (S.D.N.Y. 2011) (quoting *Gortat v. Capala Bros., Inc.*, 257 F.R.D. 353, 361 (E.D.N.Y. 2009), *aff'd*, 568 F. App'x 78 (2d Cir. 2014)). Nevertheless, "Rule 23 does not set forth a mere pleading standard," because – unlike other pleading standards – determining whether a class should be certified requires the submission of evidence: "A party seeking class certification must affirmatively demonstrate . . . that there are *in fact* sufficiently numerous parties, common questions of law or fact, etc." *Wal-Mart*, 564 U.S. at 351.

"The party seeking class certification bears the burden of establishing by a preponderance of the evidence that each of Rule 23's requirements has been met." *Myers v. Hertz Corp.*, 624 F.3d 537, 547 (2d Cir. 2010); *see also In re U.S. Foodservice Inc. Pricing Litigation*, 729 F.3d 108, 117 (2d Cir. 2013). SBA and Defendants have thus each submitted expert reports in support of their position, and the Court will seek to resolve the "factual disputes relevant to each Rule 23 requirement" to see if each has been met. *In re Initial Public Offerings Secs. Litig.*, 471 F.3d 24, 41 (2d Cir. 2006).

III. DISCUSSION

A. Defendants' *Daubert* Motion to Exclude the Opinions of Dr. William Vogt is Denied

Defendants move to exclude the opinions of SBA's expert Dr. William Vogt. Specifically, they wish to exclude (1) his estimate of the date of market entry of generic Namenda had there been no reverse payments, and (2) his damages calculation based off of that estimated date of

entry. This motion was filed as part of this case's summary-judgment proceedings, but since Dr. Vogt's opinions are relevant to class certification, a *Daubert* analysis is necessary. The motion is denied.

1. Dr. Vogt's Opinions

Dr. Vogt estimates that, but-for the reverse payments, generic Namenda IR would have entered the market in November 2012, more than two and a half years before the July 2015 date of actual generic launch. Vogt determined this but-for date after assessing the relative bargaining strengths of Forest and Mylan – who, in July 2010, became the last generic manufacturer to settle with Forest. (Vogt Report at ¶ 117). Since all of the reverse settlements permitted the settling manufacturer to enter the market as soon as any other generic manufacturer launched its version of generic Namenda, Mylan's ultimate permitted entry date of July 2015 governed the actual date of generic entry.[1] (*Id*. at ¶ 33).

Vogt used a Nash Equilibrium bargaining model to estimate the but-for generic-entry date had the two parties not settled on reverse-payment terms but proceeded to litigate. To construct his model, he used the actual terms of the parties' settlement to estimate each party's relative bargaining strength. He then factored this estimate of relative bargaining strength, along with other factors – such as the companies' profit projections given different dates of generic entry – to predict the but-for date of generic entry. He also considered the strength of Mylan's claim that any generic it created would either not infringe Forest's patent, or that Forest's patent was invalid. While Vogt arrived at a but-for generic-entry date of November 2012, his model "is capable of producing

[1] Forest and Mylan ultimately settled for a generic-entry date in January 2015, with a six-month extension of that date if Forest successfully obtained a six-month extension to its '703 Patent. Since Forest successfully obtained the extension, the final date of generic entry was pushed back six months to July 2015.

estimates of damages for any but-for entry date after January, 2011 up to July, 2015" and can factor in "various combinations of Forest's conduct in the but-for world." (*Id*. at ¶ 97).

Vogt then used his estimate of the but-for generic-entry date to calculate the aggregate class-wide damages TPPs likely suffered from the reverse payments. He calculates these overcharges by "comparing the price paid by Class members during the period of alleged misconduct with the prices for that same product in another period where the price was not impacted by the alleged misconduct." (*Id*. at ¶ 65). This type of "benchmark" methodology is commonly used to calculate damages, and in this case, "the period after the actual entry of generic memantine can be used as a reliable benchmark period." (*Ibid*.) For example, Vogt observed that the price of generic Namenda "fell rapidly" after entering the market at a price of $7.79 per day of therapy ("DOT"), so that, one year after entry, the average price of a Namenda generic was $5.56 per DOT, and $5.40 per DOT two years after entry. He then used these price movements to calculate the but-for price of memantine had generics entered the market in November 2012, when Namenda IR prices were around $8.91 per DOT. Ultimately, he used the difference in the actual and but-for prices to calculate the level of overcharges attributable to the delayed entry.

Brand-generic "overcharges occur because patients who would have (in a but-for world) consumed generic memantine instead consumed branded Namenda IR" during the period in which generic entry was delayed. (*Id*. at ¶ 54). These patients (and TPPs) "pay the price difference between Namenda IR and its generic equivalent times the volume of brand Namenda IR consumed which would have been replaced by generic memantine in the but-for world." (*Ibid*.). Generic-generic overcharges also occur. This happens because "the price of a generic drug . . . falls rapidly" due to increased competition among generic manufacturers from the time it enters the market until it settles a few years later. (*Id*. at ¶ 55). The reverse payments deferred this falling price action for

the period that generic entry was delayed. The overpayment for generic-generic overcharge "is the volume of generic drug consumed times the price difference of generics between the actual and but-for worlds." (*Ibid*.).

2. Dr. Vogt's Opinions are Admissible

Dr. Vogt is qualified to opine about the economic factors at play that determine a possible date of generic entry, as well as the resulting damages that may be attributable to an impermissibly delayed entry. He has a Ph.D. in economics from Stanford University, and has served an Associate Professor of Economics at the Carnegie Mellon University and the University of Georgia. He has also worked as a Senior Economist at the RAND Corporation. He currently works for Acumen, LLC, a healthcare policy consulting firm. (ECF 595 at pg. 2). Defendants do not contest that Dr. Vogt is unqualified as an economics expert who can offer his views on economic modeling.

Dr. Vogt's methodology is also sufficiently reliable to pass muster under *Daubert*. He derives his opinions using a widely recognized economic bargaining model, one quite similar to the model used by Professor Einer Elhauge, whose expert opinion was deemed reliable in the corresponding direct-purchaser action. *Namenda V*, 331 F. Supp.3d at 173–74. Vogt's estimates of the parties' relative bargaining powers are based on of the actual reverse-payment settlement that the parties entered into, and he also used calculations of the estimated potential profits that each party had to gain/lose pursuant to a settlement or no settlement. In short, there is no reason to conclude that the model itself is flawed.

Notably, Defendants do not contest that economic bargaining models in general are unreliable. They only contend that Dr. Vogt has misapplied certain assumptions to make his determination of the but-for date of generic entry. For instance, they claim that Vogt incorrectly interpreted the report of another expert to come to a determination that Mylan had a 92.5% chance

of prevailing in its defense of Forest's patent-infringement litigation – which he then factored into his analysis of the but-for generic-entry date.

This is a classic example of what this Court calls, "That expert's testimony hurts our case, so let's try to disqualify the expert" use of *Daubert*. A *Daubert* inquiry is designed to weed out unreliable methodologies – "junk science" – not to be a substitute for cross-examination about the validity of an analysis that uses established methodologies. All that matters at this stage of the litigation is that Dr. Vogt's model in estimating the damages associated with the differing dates of entry is sufficiently reliable so that it can yield data on which a jury can rely if it is applied correctly.

Economic bargaining models have been upheld as reliable in other antitrust cases. *See, e.g.*, *United Food and Com. Workers Local 1776 & Participating Emps. Health and Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1188 (N.D. Cal. 2017). And the use of an aggregate model to estimate damages "is well established in federal court and implied by the very existence of the class action mechanism itself." *Hickory Secs. Ltd. v. Republic of Argentina*, 493 F. App'x 156, 159 (quoting *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 197–98 (1st Cir. 2009)). The fact that Defendants have not mounted an attack on the model itself ends the *Daubert* inquiry.

Defendants are free at trial to explore Dr. Vogt's application (or misapplication) of the model. Like Professor Elhauge in the direct-purchaser action, Dr. Vogt will have to qualify any opinion he makes by testifying that "it would have been economically rational for both parties to enter" a settlement "in a but-for world by specific dates, not that they necessarily *would have*." *Namenda V*, 331 F. Supp. 3d at 174 (internal quotation marks omitted). Defendants will be able to cross-examine Vogt about his conclusions and assumptions when he testifies, and the jury will be

free to accept or reject his estimates of the but-for date of entry as they will be the ones who will ultimately determine the valid but-for date of generic entry.

Defendants' motion to exclude Dr. Vogt's opinions is denied.

B. Rule 23(a) Factors

1. Numerosity

Rule 23(a)(1) requires that the proposed class be "so numerous that joinder of all members is impracticable." Although "the numerosity inquiry is not strictly mathematical but must take into account the context of the particular case," it "is presumed for classes larger than forty members." *Pa. Public Sch. Emp's Ret. Sys. v. Morgan Stanley & Co., Inc.*, 772 F.3d 111, 120 (2d Cir. 2014).

The number of prescriptions of Namenda and its generics during the proposed class period likely numbers in the millions. The number of TPPs providing reimbursement for these purchases is likely to be in the thousands. According to Defendants' expert Dr. James W. Hughes, in a data set he analyzed provided by OptumRx, a major Pharmacy Benefit Manager ("PBM") that processed insurance claims for TPPs, there were at least 1,659 distinct third-party entities that claimed reimbursement for memantine purchases during the class period. (Hughes Report at ¶ 137). This does not even account for other TPPs who may have processed claims with other PBMs. Accordingly, joinder of all TPPs that qualify for class membership would be impracticable. The numerosity requirement is met.

2. Commonality

Rule 23(a)(2) requires that there be "questions of law or fact common to the class." This requirement "is satisfied if there is a common issue that 'drive[s] the resolution of the litigation' such that 'determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke.'" *Sykes*, 780 F.3d at 84 (quoting *Wal-Mart*, 564 U.S. at 50)). Most importantly, "Commonality requires the plaintiff to demonstrate that the class members have

suffered the same injury" such that their claims "depend upon a common contention" that "is capable of classwide resolution." *Wal-Mart*, 564 U.S. at 349–50 (internal quotation marks and citation omitted).

Where, as here, a plaintiff moves for certification under Rule 23(b)(3), which requires an assessment of whether common questions predominate, "the commonality requirement is subsumed under, or superseded by, the more demanding predominance requirement of Rule 23(b)(3)." *Namenda V*, 331 F. Supp. 3d at 203. If the predominance requirement is satisfied, then so will the commonality requirement. *See* Section III.D.1, *infra*.

3. Typicality

Rule 23(a)(3) requires that "the claims or defenses of the representative parties are typical of the claims or defenses of the class." This requirement "is satisfied when each class member's claim arises from the same course of events, and each class member makes similar legal arguments to prove the defendant's liability." *Marisol A. v. Giuliani*, 126 F.3d 372, 376 (2d Cir. 1997) (internal quotation marks omitted) (quoting *In re Drexel Burnham Lambert*, 960 F.2d 285, 291 (2d Cir. 1992)).

Defendants claim that as the class's claims arise under a variety of state laws, a finding of typicality is precluded because SBA's claims may not be typical of claims brought by class members in other states. This argument is better suited to whether common issues of law and fact predominate over the class, and does not preclude a finding of typicality. The typicality consideration requires only that each class member makes similar legal arguments, not identical ones. *See, e.g.*, *Robidoux v. Celani*, 987 F.2d 931, 936 (2d Cir. 1993). "[M]inor variations in the fact patterns underlying individual claims" will not derail the typicality requirement so long as plaintiffs "alleged that the same unlawful conduct was directed at or affected both the named plaintiff and the class sought to be represented." *Id*. at 936–37.

Here, each TPP class member's claims clearly arise out of the same course of events – Defendants' actions surrounding Namenda. These actions harmed TPPs by forcing them to pay supracompetitive prices for memantine. SBA's allegations are not in any way "subject to unique defenses which threaten to become the focus of the litigation." *In re Digital Music Antitrust Litig.*, 321 F.R.D. 64, 87 (S.D.N.Y. 2017) (citation omitted). Despite the claims arising from the antitrust laws of different states, "proof of anticompetitive conduct establishes a violation of each state's laws." *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2017 WL 4621777, at *20 (D. Mass. Oct. 16, 2017). Since SBA's allegations are no different from any other class member's, slight variations in the antitrust laws of various states (and they are slight indeed, *see* Section III.D.1.*iii*, *infra*) do not make SBA's claims atypical. The substantive proof of any anticompetitive conduct arising from SBA's theories of liability will be relevant to all class members and will be typical to any class member that wishes to bring a suit individually.

Several other courts have found the typicality requirement satisfied in indirect-purchaser cases arising under various state laws. *See, e.g., In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 335 F.R.D. 1, 29–30 (E.D.N.Y. 2020) (certifying a class of end-payor plaintiffs whose claims arose from the antitrust laws of more than thirty states); *In re Nexium (Esomeprazole) Antitrust Litig.*, 297 F.R.D. 168, 176 (D. Mass. 2013) (certifying a class of end payors whose claims arose under the antitrust laws of twenty-six states).

Thus, the typicality requirement is met because SBA must prove the existence of an antitrust conspiracy, that the conspiracy caused injury, and that it resulted in damages. These requirements are typical to what all class members must prove.

4. Adequacy of Representation

Rule 23(a)(4) requires that "the representative parties will fairly and adequately protect the interests of the class." This entails an "inquiry as to whether: 1) plaintiff's interests are antagonistic

to the interest of other members of the class and 2) plaintiff's attorneys are qualified, experienced and able to conduct the litigation." *In re Flag Telecom Holdings, Ltd. Secs. Litig.*, 574 F.3d 29, 35 (2d Cir. 2009) (quoting *Baffa v. Donaldson, Lufkin & Jenrette Sec. Corp.*, 222 F.3d 52, 60 (2d Cir. 2000)). The requirement ensures that any potential conflicts of interest will be uncovered, but to defeat certification, a conflict must be "fundamental" and go "to the very heart of the litigation." *Charron v. Wiener*, 731 F.3d 241, 250 (2d Cir. 2013) (citation omitted). "Not every conflict among subgroups of a class will prevent class certification." *In re Literary Works in Elec. Databases Copyright Litig.*, 654 F.3d 242, 249 (2d Cir. 2011).

Before SBA amended its class definition, Defendants argued that SBA could not adequately represent the class because the interests of TPPs like SBA conflicted with those of individual consumers. Since individual consumers are no longer encompassed within the class definition, this argument falls away.

This is not an instance in which SBA seeks a completely different form of relief from other plaintiffs (i.e., monetary relief versus injunctive relief), or one where some of the plaintiffs stand to benefit more than others from a particular resolution of the case. *See In re Payment Card Interchange Fee and Merchant Discount Antitrust Litig.*, 827 F.3d 223, 233–34 (2d Cir. 2016).

SBA's counsel are sufficiently qualified and experienced to conduct the litigation. They have extensive experience representing other named plaintiffs in antitrust class actions and have competently represented SBA in these proceedings.

The adequacy of representation requirement is met.

C. Ascertainability

To be ascertainable, a proposed class "must be readily identifiable, such that the court can determine who is in the class and, thus, bound by the ruling." *In re Scotts EZ Seed Litig.*, 304 F.R.D. 397, 407 (S.D.N.Y. 2015) (quoting *Charron v. Pinnacle Grp. N.Y. LLC*, 269 F.R.D. 221,

229 (S.D.N.Y. 2010)). Not all class members need to be identified by the time of certification, but the boundaries of the class need to be "readily identifiable." *In re Petrobras*, 862 F.3d at 266. In contrast to at least one other Court of Appeals, the Second Circuit does not require that the proposed class be "administratively feasible," *id*. at 265, only that the determinations outlining the boundaries of the class "are objectively *possible*." *Id*. at 270; *compare with City Select Auto Sales Inc. v. BMW Bank of North Am. Inc*., 867 F.3d 434, 440–41 (3d Cir. 2017). As a result, "The standard for ascertainability is 'not demanding' and is 'designed only to prevent the certification of a class whose membership is truly indeterminable.'" *Ebin v. Kangadis Food Inc*., 297 F.R.D. 561, 567 (S.D.N.Y. 2014) (quoting *Gortat v. Capala Bros., Inc.*, No. 07-cv-3629 (ILG), 2010 WL 1423018, at *2 (E.D.N.Y. Apr. 9, 2010).

SBA's expert, Ms. Laura R. Craft, opines that the proposed class is not only ascertainable, but that identifying the class members would be "a largely programmatic exercise that depends only on data routinely kept (and legally mandated) in the pharmaceutical industry, and which is characterized by extraordinarily high levels of standardization." (Craft Report at ¶ 1). Although I will provide a brief summary of Craft's opinions in support of ascertainability, a more detailed explanation is contained in my opinion and decision denying Defendants' motion to exclude Craft's opinions from the class-certification analysis. *See Namenda VII*, 2021 WL 100489, at *8.

Federal regulations require highly detailed information to be kept regarding each prescription drug purchase, including the individual consumer and the third-party payor (i.e., potential class member) that provides reimbursement for the purchase. This common data is kept by three institutional sources: (1) the pharmacy that dispenses the drug; (2) the Pharmacy Benefit Manager ("PBM") that processes the insurance claims associated with the purchase; and (3) the third-party payor. Because of the enormous number of pharmacies that TPPs will need to interact

with to provide reimbursement, TPPs hire PBMs to help process their insurance claims. The PBM industry is highly concentrated and contain only a few main players. Although each of the three institutional entities listed above can supply the information necessary to ascertain potential TPP class members, the few number of PBMs that process the vast majority of insurance claims in the U.S. provide a centralized source to obtain the information necessary to ascertain the class. Once this data is collected and aggregated, all TPP class members that paid for any purchase of memantine can be identified.

For instance, Craft detailed how this can be accomplished by analyzing a tranche of data provided by OptumRx, a major PBM. The data contained transaction-specific information regarding all of the memantine sales that Optum processed, with fields identifying both the individual consumer purchaser and the third-party entity providing reimbursement for that specific purchase. Identifying the TPP that paid reimbursement for the memantine purchase would be no more of a task than simply collecting these sets of information, and then analyzing the data to identify the TPP.

Class members subject to the relevant class exclusions can be identified through this process as well. For instance, Craft notes that PBMs processing the insurance claims would know the identity of any government entities (exclusion (c)) that they service. (*Id*. at ¶ 77). Information about state/federal insurance plans is also publicly available, and so whoever is analyzing the raw PBM data could use this information to apply the exclusion. (*Id*. at ¶¶ 78–80). Fully-insured plans (exclusion (b)) – plans that purchased insurance from another TPP that covered all of the insured's payments – can be identified through several identification numbers attached to each drug purchase. These numbers – the Bank Identification Number and the Processor Control Number –

direct the electronic routing system processing the claim to charge the correct entity and can be used to identify the ultimate payor of the claim. (*Id*. at ¶ 54).

Defendants argue that Ms. Craft's opinions cannot be relied upon because she acknowledges that she has not personally obtained the data necessary to carry out her methodology, nor has she ever done so before to determine an indirect-purchaser class. But "ascertainability does not require a complete list of class members at the certification stage." *In re Petrobras*, 862 F.3d at 266 n.16 (citation omitted). There is no requirement that the class actually have already been identified – or that the methodology to identify the class need to have already been carried out – by the time of certification. All that matters is that ascertaining the class is "objectively *possible*," and that requirement is "modest." *Id*. at 270.

For example, a class definition may be "insufficiently bounded" if it encompasses any entity "owning a beneficial interest in a bond series without reference to time owned" because the class would arguably be open and thus subject to fluctuations in size and membership. *Id.* at 266 (quoting *Brecher*, 806 F.3d at 25). Such an imprecise definition – without reliance upon any objective criteria upon which to determine membership – made it impossible to identify who would be bound by the judgment.

No similar situation arises in this case. The proposed class is not indeterminate or subject to open. Only TPPs that paid reimbursement for memantine from June 1, 2012 to December 31, 2017 can be a part of the class. Those two requirements are "objective criteria" such that it provides a clear boundary to delineate certain TPPs from others. The class definition provides "a clear sense of who is suing about what," as the time frame and reimbursement criteria are obviously tied to SBA's theories of liability underpinning its case. *Id*. at 269. In short, if an entity purporting to be

a class member attempts to collect on any award, application of the proposed class definition will easily enable a claims administrator to determine whether the entity is or is not a class member.

The primary focus of the ascertainability requirement is whether the class "is *defined* using objective criteria that *establish a membership with definite boundaries*." *Id*. at 257 (emphasis added). Defendants do not argue that the class is *defined* ambiguously or that it would lead to uncertainty about which entity may or may not be in the class. Instead, they argue that – because Craft has not already identified the class members – it would be administratively infeasible to identify all of the members before trial. But the Second Circuit has refused to heighten the ascertainability threshold to require that the class be "administratively feasible." *Id*. at 266. It is a "modest" requirement that does not go so far. *See, e.g., B & R Supermarket, Inc. v. Mastercard Int'l, Inc.*, No. 17-cv-2738 (MKB), 2021 WL 234550, at *19 (E.D.N.Y. Jan. 19, 2021) (noting that the Second Circuit has "explicitly rejected" a feasibility requirement). Although this class is likely to number in the thousands, that is irrelevant to whether the identity of class members can be ascertained. SBA has offered a definitive way to identify the TPPs and have demonstrated that the information necessary to do so exists and can be collected from several institutional sources.

As I stated in the decision denying Defendants' *Daubert* motion, "just because the class members have not yet been identified does not mean they cannot be identified" before trial. *In re Namenda*, 2021 WL 100489, at *12. The implied requirement of ascertainability is met.

D. Rule 23(b) Factors

1. Predominance

Class certification under Rule 23(b)(3), requires that "questions of law or fact common to class members predominate over any questions affecting only individual members." The predominance inquiry is similar to that of commonality under Rule 23(a), but the standard "is far more demanding," *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 623-24 (1997), "and is not

satisfied simply by showing that the class claims are framed by the common harm suffered by potential plaintiffs." *In re Petrobras*, 862 F.3d at 270. Instead, predominance requires a showing that: "(1) resolution of any material legal or factual questions can be achieved through generalized proof, and (2) these common issues are more substantial than the issues subject only to individualized proof." *Ibid*; *see also In re U.S. Foodservice Inc. Pricing Litig*., 729 F.3d at 118.

A common question is one where "the same evidence will suffice for each member to make a prima facie showing [or] the issue is susceptible to generalized, class-wide proof," while an individualized question is one where class members "will need to present evidence that varies from member to member." *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1045 (2016) (quoting 2 W. Rubenstein, Newberg on Class Actions § 4:50, pp. 196–197 (5th ed. 2012)). In other words, evidence is common if any class member can use it to prove its claim against the defendants, whereas individual evidence is only applicable to that specific member, and is irrelevant to the claims of the other class members.

The requirement that common questions be "more substantial" than individual ones naturally means that "predominance is a comparative standard" *In re Petrobras*, 862 F.3d at 268. "The mere existence of individual issues will not suffice to defeat certification. Rather, the balance must tip such that these individual issues predominate." *Sykes*, 780 F.3d at 87. This ensures that only "fatal" differences among class members, which may "make use of the class-action device inefficient or unfair," will derail certification. *Amgen, Inc. v. Connecticut Retirement Plans and Trust Funds*, 133 S. Ct. 1184, 1197 (2013).

i. Predominance in Antitrust Class Actions

Determining whether common questions of law or fact predominate requires specifically evaluating "the elements of the underlying cause of action." *Erica P. John Funds, Inc. v. Halliburton Co.*, 563 U.S. 804, 809 (2011). There are three elements for all antitrust claims: (1) a

violation of the antitrust laws; (2) injury caused by that violation; and (3) measurable damages. *Cordes & Co. Fin. Servs., Inc. v. A.G. Edwards & Sons, Inc.*, 502 F.3d 91, 105 (2d Cir. 2007).

The first element, a violation of the antitrust laws, requires that the alleged conduct – if proven – amounts to illegal activity under the antitrust laws. Generally, this element includes analyses of "the geographic market definition, the product market definition," the defendants' "monopoly power" and the extent of the alleged anticompetitive conduct. *Dial Corp v. News Corp.*, 314 F.R.D. 108, 114 (S.D.N.Y. 2015). Because it is primarily a determination that focuses on the defendants' conduct – i.e., whether the conduct alleged would actually violate the antitrust laws – common evidence generally predominates over individualized evidence with regard to this element. *See, e.g., In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124, 136 (2d Cir. 2001).

The second element, antitrust injury, asks whether plaintiffs "can prove, through common evidence, that all class members were . . . injured by the alleged conspiracy." *Sykes*, 780 F.3d at 82 (quoting *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 725 F.3d 244, 252 (D.C. Cir. 2013)). This element has been termed "antitrust injury," antitrust "impact," or "impact and causation." *In re Aluminum Warehousing Antitrust Litig.*, 336 F.R.D. 5, 44 (S.D.N.Y. 2020). Ultimately, it focuses on how plaintiffs were harmed.

The Second Circuit has held that "the second element of an antitrust cause of action – 'antitrust injury' – poses two distinct questions." *Cordes*, 502 F.3d at 106. The first question "is the familiar factual question whether the plaintiff has indeed suffered harm, or 'injury-in-fact.'" *Ibid*. The second question "is the legal question whether any such injury is 'injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful.'" *Ibid*. (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489

(1977)). Because the second question is one of law and is similar to the question of whether there has been a violation of the antitrust laws, the antitrust-injury element generally focuses on whether plaintiffs have all suffered the same injury-in-fact. *See In re Aluminum Warehousing*, 336 F.R.D. at 46.

The last element is that there be measurable damages attributable to a plaintiff's theory of liability. In *Comcast v. Behrend*, 569 U.S. 27 (2013), the Supreme Court "held that a model for determining classwide damages relied upon to certify a class under Rule 23(b)(3) must actually measure damages that result from the class's asserted theory of injury." *Roach v. T.L. Cannon Corp.*, 778 F.3d 401, 407 (2d Cir. 2015). This means that a damages estimate proffered by a plaintiff's expert must actually correspond to the specific theory of liability that plaintiffs advance. "If the model does not even attempt to do that, it cannot possibly establish that damages are susceptible of measurement across the entire class for purposes of Rule 23(b)(3)." *Comcast*, 569 U.S. at 35. Courts are thus obligated to conduct a "rigorous analysis" to ensure that plaintiffs satisfactorily "tie each theory of antitrust impact to a calculation of damages." *Ibid*. (internal quotation marks omitted).

That is not to say, however, that a class cannot be certified "where damages are not capable of measurement on a classwide basis," *Roach*, 778 F.3d at 409, or that all plaintiffs must have incurred the same amount of damages, or that there can be no individualized inquiries when damages are actually disbursed. "Typically, common issues predominate when liability is determinable on a class-wide basis, *even where class members have individualized damages*." *B & R Supermarket*, 2021 WL 234550, at *21 (emphasis added). The Second Circuit has held that, "*Comcast* reiterated that damages questions should be considered at the certification stage when weighing predominance issues, but this requirement is entirely consistent with our prior holding

that 'the fact that damages may have to be ascertained on an individual basis is . . . a factor that we must consider in deciding whether issues susceptible to generalized proof "outweigh" individual issues.'" *Roach*, 778 F.3d at 408 (quoting *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 231 (2d Cir. 2008), *abrogated in part on other grounds by Bridge v. Phx. Bond & Indem. Co.*, 553 U.S. 639, 128 S.Ct. 2131, 170 L.Ed.2d 1012 (2008)). This means that a class will be certified if the substantive issues regarding liability predominate over the individualized issues that will affect only damages. All that matters is that the questions of law and fact relevant to determining damages are common to the class, and that a damages estimate "roughly reflect[s] the aggregate amount owed to class members." *Seijas v. Republic of Argentina*, 606 F.3d 53, 58-59 (2d Cir. 2010).

Generally speaking, predominance is a "test readily met in certain cases alleging . . . violations of the antitrust laws." *Amchem*, 521 U.S. at 625. At first glance, this lawsuit appears to be just such a case. All members of the proposed class allege that Defendants' actions forced all of them to pay supracompetitive prices for memantine, and thus evidence of market demand and memantine prices will be evidence that is common to the class.

Although it is possible – indeed, it is likely – that each TPP plaintiff will have to prove whether and by how much it was harmed in order to collect damages, that alone does not preclude certification. "Common issues may predominate when liability can be determined on a class-wide basis, even when there are some individualized damage issues." *In re Visa Check*, 280 F.3d at 139. Courts have routinely certified antitrust class actions where individual damages issues exist. *See, e.g., Ibid; Cordes*, 502 F.3d at 108. "When 'one or more of the central issues in the action are common to the class and can be said to predominate, the action may be considered proper under Rule 23(b)(3) even though other important matters will have to be tried separately, such as damages or some affirmative defenses peculiar to some individual class members.'" *Tyson Foods*,

136 S. Ct. at 1045 (quoting 1AA C. Wright, A. Miller, & M. Kane, Federal Practice and Procedure § 1778, pp. 123–124 (3d ed. 2005) (footnotes omitted)). In short, "individual damages determinations do not defeat class certification." *Dial Corp.*, 314 F.R.D. at 120.

ii. SBA's Two Theories of Antitrust Liability

SBA advances two theories of antitrust liability: (1) Defendants' "pay-for-delay" scheme, in which reverse settlements to generic manufacturers delayed the market entry of generic memantine such that it resulted in TPPs reimbursing more for branded Namenda products that would have otherwise been generics; and (2) Defendants' "hard switch" strategy, which transferred an aberrantly large base of Namenda IR prescriptions to Namenda XR such that once generics did hit the market, they were unable to be as competitive. For both theories, SBA alleges that Defendants' actions decreased competition in the memantine market such that it forced TPP class members to pay more for memantine than would otherwise have been the case.

However, the *way* that a TPP was forced to pay higher prices through the two theories is fundamentally different. For example, the pay-for-delay scheme had the dual effect of delaying the availability of cheaper alternatives, and also decreased the level of competition among generics once they did enter the market. TPPs were injured by having to pay more for higher-priced branded Namenda IR and XR (as opposed to cheaper generics) during the time in which generic entry was delayed – so called "brand-generic overcharge"; and were also harmed by having to pay higher prices for the generics once they became available – "generic-generic overcharge." Thus, any TPP that reimbursed for either Namenda IR, XR, or a generic could have been harmed by this scheme.

This is not the same way that the hard switch harmed TPPs. Forest designed that strategy to increase the percentage of IR patients who would switch to XR, such that the XR market would be insulated from competition after the launch of IR generics. IR generics are not AB-equivalent to XR, and so a bigger base of XR users meant a smaller market shift to generic IR after generic

entry because state drug-substitution laws would be unable to automatically fill XR prescriptions with a generic. Forcing many consumers to switch from IR to XR thus depleted the base of IR prescriptions such that there were fewer generic prescriptions than there otherwise would have been. All of those would-be generic prescriptions were instead transferred to Namenda XR. The hard switch thus harmed TPPs by forcing them to provide reimbursement for many more Namenda XR prescriptions (as opposed to generic Namenda IR prescriptions) than they otherwise would have. Unlike the pay-for-delay scheme, only TPPs that would have provided reimbursement for Namenda XR during the period surrounding the hard switching (from 2014 onwards) could have been injured by this scheme – essentially an "XR-generic overcharge."

Where, as here, a plaintiff alleges more than one theory of liability, the theories must be analyzed separately to ensure that common issues predominate as to each theory. Conflating differing theories risks applying a theory of injury applicable only to certain class members to others who may not have been injured by that specific theory. In this case, for instance, there may be class members who were harmed only through Defendants' hard switch strategy, or class members who were harmed only by the pay-for-delay scheme. If each scheme injured class members in a different way, or via different mechanisms (as SBA acknowledges that they do), then conflating these two theories risks finding common issues where there are none. Common antitrust injury exists only if any "individual class member could have relied on that same evidence in an individual action." McLaughlin on Class Actions § 5:23 (17th ed.). Analyzing the theories separately guards against the possibility of one class member improperly piggybacking off of the injury caused to a different class member.

The Supreme Court has endorsed this framework for analyzing predominance in antitrust class actions. In *Comcast v. Behrend*, 569 U.S. 27 (2013), the Court held that "at the class-

certification stage (as at trial), any model supporting a 'plaintiff's damages case must be consistent with its liability case, particularly with respect to the alleged anticompetitive effect of the violation.'" *Id*. at 35 (quoting ABA Section of Antitrust Law, Proving Antitrust Damages: Legal and Economic Issues 57, 62 (2d ed. 2010)). Courts must "tie each theory of antitrust impact to a calculation of damages" so that damages are measured pursuant to "the particular antitrust injury on which [defendants'] liability in [the] action is premised." *Id*. at 35–36.

The plaintiffs in *Comcast* were cable subscribers who alleged that Comcast had entered into anticompetitive "swap agreements" with other cable providers, which allowed Comcast to obtain regional monopolies that excluded meaningful competition in several geographic areas in the United States. *Id*. at 30. The plaintiffs originally proposed four separate theories of antitrust injury, but the district court accepted only one of those theories – that Comcast's "clustering made it profitable for Comcast to withhold local sports programming from its competitors, resulting in decreased market penetration by direct broadcast satellite providers." *Id*. at 31. However, in certifying the class, the district court relied solely on the testimony of a plaintiffs' expert who calculated damages based on his presumption that generally anticompetitive activities had occurred, without "isolat[ing] damages resulting from any one theory of antitrust impact." *Id*. at 32.

The Supreme Court ruled that applying a theory of damages without limiting it to the theory of liability in question was erroneous, and that the class was improperly certified. It held that any "model purporting to serve as evidence of damages" in support of class certification "must measure only those damages attributable to th[e] theory" that the plaintiff advanced. *Id*. at 31. "If the model does not even attempt to do that, it cannot possibly establish that damages are susceptible of

measure across the entire class for purposes of Rule 23(b)(3)." *Ibid*. Put simply, proof of class-wide damages must correspond with a plaintiff's theories of liability.

Although the discussion in *Comcast* concerned the expert's analysis of measurable damages (the third element of an antitrust claim), its rationale applies equally to analyses of whether there exists common proof of class-wide injury (the second element). If many class plaintiffs cannot link their specific injury to one of the theories articulated by the lead plaintiff, then there is no guarantee that common issues predominate across the class. In other words, just because SBA could demonstrate that a putative class member *was* injured does not mean that the injury arose out of the same conduct that harmed other class members. The cause of the injury must be the same. Especially in a situation like this one, where a plaintiff advances varying theories of injury, it is important to note whether the harm arising from each theory is truly common to the class.

As my colleague, the Honorable Paul Engelmayer, has noted, "Following *Comcast*, circuit courts in antitrust cases have consistently, and correctly, read that decision to require that district courts carefully examine, at the class certification stages, the soundness of an expert's model relied upon to establish classwide *impact*." *In re Aluminum Warehousing*, 336 F.R.D. at 47 (emphasis added). And "where an expert's model of classwide injury fails, absent alternative common proof of class impact, such deficiencies will preclude class certification under Rule 23(b)(3)." *Id*. at 49.

For example, shortly after *Comcast*, the D.C. Circuit held that, "Common questions of fact cannot predominate where there exists no reliable means of proving classwide injury in fact." *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 725 F.3d at 252–53. The plaintiffs in *Rail Freight* were railroad shippers that alleged that four major railroad companies had engaged in a price-fixing conspiracy to increase shipping rates. *Id*. at 247. The district court certified a class of

shippers, but the D.C. Circuit vacated the decision, holding that the district court had inadequately scrutinized the plaintiffs' expert's model when determining that common questions of injury predominated. Upon closer examination of the model – as now required by *Comcast* – the Circuit determined that the model likely "yielded false positives with respect to" the injury suffered by certain putative class members – a key fact that was not disputed by the expert himself. *Id*. at 253. As such, the D.C. Circuit determined that the district court failed to take a "hard look at the soundness of the statistical models that purport to show predominance" and vacated the certification. *Id*. at 255.

Most recently, the Third Circuit held that a district court abused its discretion in certifying a class when it inadequately analyzed competing expert reports that discussed common injury. *See In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d 184 (3d Cir. 2020). The plaintiffs in *Lamictal* were direct purchasers of a brand-name drug. They alleged that defendant drug manufacturers entered into anticompetitive reverse-payment settlements – similar to SBA's allegations in this case. *Id*. at 192. SBA's expert explained that there was common injury by analyzing average prices in the actual and reverse payment but-for worlds, and the district court simply accepted the average-pricing data as dispositive evidence of the existence common injury, without inquiring whether, for instance, the relevant market was "characterized by individual negotiations" or whether there were other factors or events that might have resulted in a generic manufacturer's "lower[ing] its pricing" such that it made the expert's average-pricing model unreliable. *Id*. at 194. The Third Circuit concluded, "While averages may be acceptable where they do not mask individualized injury," it could not "determine whether that occurred here because of the [district court's] lack of analysis," and de-certified the class. *Id*. at 194.

Although the Second Circuit has yet to explicitly apply *Comcast*'s rationale to the question of antitrust injury, I can think of no reason why it would not do so. *Cf Sykes*, 780 F.3d at 82 (citing the D.C. Circuit's decision in *In re Rail Freight* with approval). Especially in a situation like this, in which experts' opinions are a "central basis for establishing classwide injury and causation," a district court must determine that the models provide a suitable basis for the theories of liability underpinning the plaintiffs' claims. *In re Aluminum Warehousing*, 336 F.R.D. at 49. Simply accepting the models as true, without engaging in searching analysis, risks certifying a class of uninjured plaintiffs, or a class of plaintiffs who were not injured in the same way such that common issues of law or fact predominate.

In short, "where an expert's model is the basis for a plaintiff's claim of classwide impact and causation, a court is obliged to rigorously examine the soundness of that model at the class certification stage," and "may certify a class under these circumstances only where the Court finds the model methodologically sound." *Id*. at 46. The Court will thus conduct a detailed examination of each of SBA's theories of antitrust liability, its expert's models in support of those theories, and whether the evidence of that injury is common to class members, starting with the "pay-for-delay" theory and then turning to the "hard switch" theory.

A. **Pay-for-Delay Scheme**

1. Antitrust Violation

The Supreme Court has held that reverse-payment settlements between brand-name and generic drug manufacturers can "violate the antitrust laws," and that they are not immune from antitrust scrutiny. *Actavis*, 570 U.S. at 141. Any evidence regarding the pay-for-delay scheme will focus solely on Defendants' conduct and will not vary across class members. For example, like the direct-purchaser action, "all members will need to present evidence of the agreement and its terms." *Namenda V*, 331 F. Supp. 3d at 215. And all plaintiffs can use these agreements as evidence

that Defendants' conduct was anticompetitive and violated the antitrust laws. Thus, common questions of law and fact predominate individual ones as to whether the pay-for-delay scheme violates the antitrust laws.

2. Antitrust Injury

Unlike the hard switch, *see* Section III.D.1.*ii*.B, *infra*, all TPPs that reimbursed for *any* purchase of memantine during the class period were likely harmed by the pay-for-delay scheme.

SBA's expert, Dr. Lamb, examined a counterfactual in which there had been no reverse payments and thus generic memantine entered the market earlier than July 2015. He explained that, in the no-reverse-payment but-for world, "state laws would have driven rapid substitution of generic Namenda IR hydrochloride for brand-name Namenda by pharmacists once the AB-rated generic became available." (Lamb Report ¶ 84). With earlier generic entry, there would have been increased generic competition with both Namenda IR and (eventually) XR such that "proposed Class members would have purchased generic Namenda IR earlier and in higher amounts, all at lower prices than the prices at which they purchased branded Namenda IR and/or XR" during the relevant class period. (*Ibid.*)

Generic prices would also have been lower than actual current generic prices due to the increased duration of competition among the generics. Dr. Lamb notes that it is well documented in the pharmaceutical industry that generic prices decrease rapidly within the first two years of entry, followed by a more gradual decline of prices. This meant that had there been earlier entry, even those patients "who purchased only generic Namenda IR would have paid less for the generic they purchased." (*Ibid.*).

Lamb's data comes from several sources, including: (1) his review of National Prescription Audit ("NPA") data obtained from IQVIA, Inc. – a company that tracks sales of prescription drugs

measured in dollars and units sold (*Id*. at ¶ 33); (2) Defendant Forest's own documents and internal projections (*Id*. at ¶¶ 43, 99); and (3) industry literature discussing the well-known industry understanding of what occurs once a brand-name drug goes off the "patent cliff." Any individual TPP could rely on any or all of these sources to support its claim, and thus they represent the existence of evidence that is common to the class.

From the NPA data, Lamb notes that Namenda IR sales dropped by approximately 86.9% by September 2015 – just two months after generics entered the market. (*Id*. at ¶ 89). Generics substantially penetrated the memantine market by being a cheaper alternative, but their prices continued to decrease over time. For example, Namenda IR generics entered the market at an average wholesale price of around $7.79 per day of therapy ("DOT").[2] (*Id*. at ¶ 94). By October 2015 (three months after generic entry), the average price of the generics had already decreased to around $6.10, which was approximately a little over half of what branded Namenda IR cost at the time. The average generic price continued to decrease over the course of many months such that by December 2017 – the end of the class period – the price was hovering around $5.40. (*Id*. at Fig. 4). Lamb notes that had there been earlier generic entry but-for the reverse payments, the price action observed following actual generic entry would have occurred sooner such that the lower prices would have been available well before when they were available in the actual world. In short:

> The rapid substitution of lower-priced generic Namenda IR for the higher-priced branded Namenda IR that occurred after generic entry is evidence, common to the proposed Class as a whole, that if generic entry had occurred earlier, proposed Class members would have purchased generic Namenda IR in place of branded Namenda IR, and these purchases would have been made at lower prices. (*Id*. at ¶ 92).

[2] Each day of therapy for Namenda IR consists of two doses, as Namenda IR was a twice-daily prescription. In contrast, each day of therapy for Namenda XR is only one dose, as it was a once-daily prescription.

Lamb notes that earlier entry of IR generics also would have impacted the Namenda XR market. Although the decline in XR market share was not as sharp as that for IR, Namenda XR still experienced "a 'slow decline' over time, primarily losing share to generic Namenda IR in the form of new starts (as opposed to reverse commuting)." (*Id*. at ¶ 93). Even though there were no generic versions of Namenda XR, IR generics competed with XR because patients newly prescribed to memantine opted for the cheaper generic options rather than the more expensive branded option. Even though Namenda XR was a once-daily rather than twice-daily dose, new patients likely opted to start "on generic Namenda IR at much lower prices." (*Id*. at ¶ 93).

Lamb's analysis of the NPA average-pricing data is supported by the industry literature, which has often documented the effects of what occurs when a brand-name drug goes off the "patent cliff." For example, Lamb described several academic studies, all of which found that even the most conservative estimates of generic market share following generic entry were more than sixty percent three months following entry. (*Id*. at ¶ 102). Lamb also cites internal documents obtained from Forest, which show that Forest executives were aware of the threat that generic competition posed; Forest's own internal projections forecast fears that the Namenda franchise would go "into decline" after generic entry. (*Id*. at ¶ 99).

In short, Lamb concludes that, but for the reverse-payment settlements, generics would have penetrated the memantine market before July 2015 (well before, per his estimate), leading to earlier availability of cheaper alternatives to Namenda, and for a longer period of time. This is because delayed generic entry delayed the availability of cheaper alternatives, leading to both "brand-generic" overcharges and "generic-generic" overcharges that were borne by all proposed members of the class. Importantly, any TPP that reimbursed for memantine during the class period would likely have suffered these injuries resulting from the delayed generic entry. This is in stark

contrast to the hard switch theory, in which only TPPs that reimbursed for Namenda XR could have been harmed. *See* Section III.D.1.*ii*.B, *infra*.

Defendants' Objections

Defendants rely primarily on the opinions of their expert, Dr. James W. Hughes, who claims that the use of average-pricing data is unreliable in a complicated market like the one for memantine, and so is likely to yield false positives of injury. Because the cost of a prescription is generally split between several different entities – only one of which is a TPP class member – Dr. Hughes notes that the relevant question is whether each TPP's *share* of payment for memantine was "higher in the actual world compared to the but-for world" – not whether average prices were generally higher. (Hughes Report at ¶ 37). He points out that, if the actual price paid by a TPP would not have been lower in the but-for world, then the TPP could not have been harmed and should be excluded from the class. Defendants insist that ascertaining the actual price paid by TPPs is a question that requires individualized inquiry.

Defendants advance several arguments as to why that will be the case: (1) reliance on average-pricing data cannot account for manufacturer rebates, which could have resulted in the actual price paid by any specific TPP being less than the cost of a generic; (2) reliance on average-pricing data cannot account for the presence of government co-payors, which decreased the cost to TPPs such that some may have been uninjured; (3) SBA does not account for "brand loyalists" – consumers who never switched to generic versions of Namenda IR, regardless of price; and (4) Lamb's model fails to account for generic-only purchasers and any overcharges that may have been passed onto from the TPPs to direct consumers.

In connection with the "pay for delay" theory, none of these arguments is convincing to preclude a finding of predominance.

a. Rebates

Hughes's first claim is that Forest provided several hundred million dollars' worth of rebates for Namenda, which had the effect of decreasing the price paid by TPPs such that the actual net price paid may have been less than the cost of a generic. Defendants insist that determining which TPPs actually paid less for brand Namenda than the generic requires individualized inquiry.

Due to varying market conditions, it is common for drug manufacturers to "pay rebates and offer discounts" throughout the supply chain – mainly through the Pharmacy Benefit Managers with which they negotiate drug prices. Depending on the market, manufacturer rebates "can be substantial." (*Id*. at ¶ 53). According to Hughes, Forest paid approximately $978 million in rebates for Namenda IR and $837 million in rebates for XR between June 1, 2012 and December 31, 2016. (*Id*. at ¶ 92). He then compared the total rebate volume to the total retail sales of Namenda during the class period. For IR, rebates ranged from 20% to nearly 25% of sales from 2012 to 2015. (*Id*. at ¶ 206). For XR, rebates ranged from 20% to 38% of sales between 2013 and 2016. (*Ibid*.). Given the rebates, Hughes believes that "the net price of brand Namenda IR and Namenda XR after rebates" for TPP class members "could be lower than the but-for prices for generic Namenda IR" absent the alleged anticompetitive conduct. (*Ibid*.).

Hughes analyzed data from OptumRx, a major PBM, which showed that the average amount TPPs paid for each DOT of Namenda XR in 2016 (before rebates) was $9.33. (*Id*. at ¶ 261). However, Hughes believes that some TPPs suffered no injury, because the amount they reimbursed for branded XR was actually less than the but-for price of the generic alternatives. For example, the bottom 10th percentile in the OptumRx data for the amount paid by TPPs – before applying any rebates – was $4.34, which would have been less than the average but-for generic price that SBA's expert, Dr. Vogt, identified. (*Ibid*.). Hughes concludes that individualized

inquiries will be needed in order to identify and exclude potential class members who suffered no injury.

But Dr. Hughes's analysis does not demonstrate why individualized would predominate over common ones in terms of ascertaining whether there was antitrust *injury*.

First, an "antitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset." *In re Nexium Antitrust Litig.*, 777 F.3d 9, 27 (1st Cir. 2015). "Paying an overcharge caused by the alleged anticompetitive conduct on a single purchase suffices to show – as a legal and factual matter – impact or fact of damage." *Ibid.* (citation omitted). In other words, antitrust injury flows from the overcharge itself. Setoffs that are applied later are relevant to the amount of damages a class member incurs, but a TPP that incurs an initial overcharge incurs injury, even if that injury is subsequently reduced. *See Hawaii v. Standard Oil Co. of Cal.*, 405 U.S. 251, 262 n.14 (1972) ("[D]amages are established by the amount of the overcharge" and "courts will not go beyond the fact of this injury to determine whether the victim of the overcharge has partially recouped its loss in some other way"). Even if a TPP were able to use a rebate to offset an initial overcharge, it would not negate the fact that the TPP suffered antitrust injury at the moment it was required to pay more for memantine than it otherwise would have but for Defendants' allegedly anticompetitive conduct. Several courts have accepted this rationale to conclude that post-overcharge rebates are insufficient to disprove antitrust injury. *See In re Restasis*, 335 F.R.D. at 29; *In re Loestrin 24 FE Antitrust Litig.*, 410 F. Supp. 3d 352, 393 (D. R.I. 2019); *In re Lidoderm Antitrust Litig.*, 2017 WL 679367 at *21; *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2017 WL 4621777 at *18; *In re Delta/AirTran Baggage Fee Antitrust Litig.*, 317 F.R.D. 675, 683 (N.D. Ga. July 12, 2016).

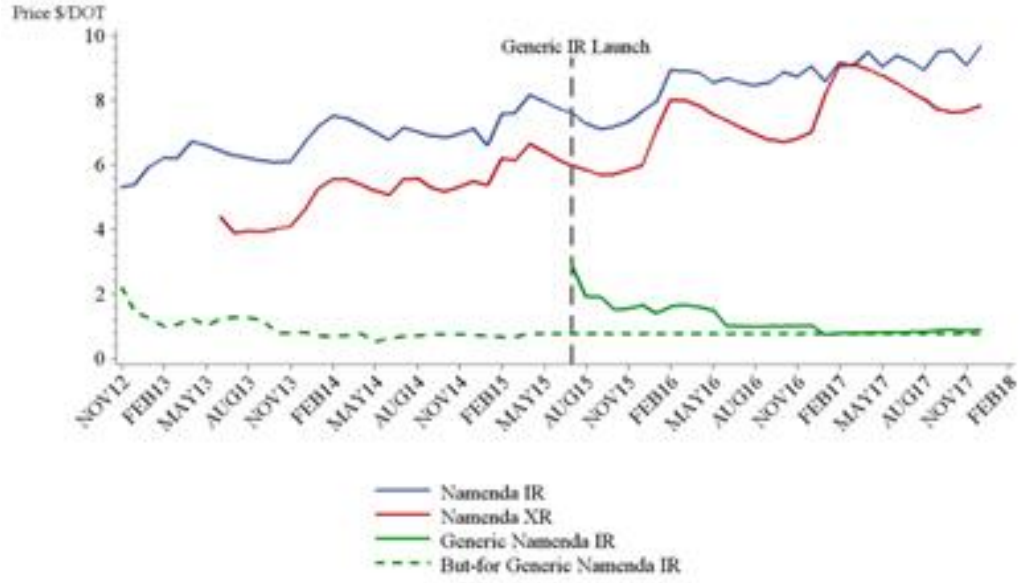
There is no indication in the record presently before the Court that any rebates Forest paid for Namenda were paid to a TPP before the TPP was overcharged. In fact, Dr. Hughes acknowledges that any rebates a TPP would have received are likely to be paid first to the *PBMs* that negotiate the drug prices with the manufacturer. The PBMs then may or may not choose to pass those rebates along to the TPPs. This is a matter of contract between the PBM and the TPP, and thus some PBMs may share none of the rebate while others may pass along a great deal. (Hughes Report at ¶¶ 62–64). There is no indication that the rebates were such that – even if they were passed on – that it would have prevented a majority of the TPP class from suffering any type of overcharge injury.

Another expert, Laura Craft, states that in her experience, "PBM/TPP agreements are typically structured as a minimum dollar amount per prescription payable on average across *all branded drugs* reimbursed under the TPP's plan or, in some cases, *both brand and generic prescriptions*. Such guarantees are never specific to an individual drug, [and] are applied to the entire portfolio of branded drugs (or sometimes brand plus generic) reimbursed by the TPP." (Craft Rebuttal at ¶ 79) (emphasis added). This suggests that any rebates that a TPP may have received from a PBM were processed *after* a TPP has already reimbursed for the drug, meaning that by the time of offset it has already incurred an overcharge and thus suffered an antitrust injury. Although I cannot conclude that *no* TPP ever ended up paying less than it would have for a generic because it received a rebate, Defendants present no definitive evidence that a majority of TPPs – or even a sizeable minority – did not suffer any injury because they received rebates before being overcharged.

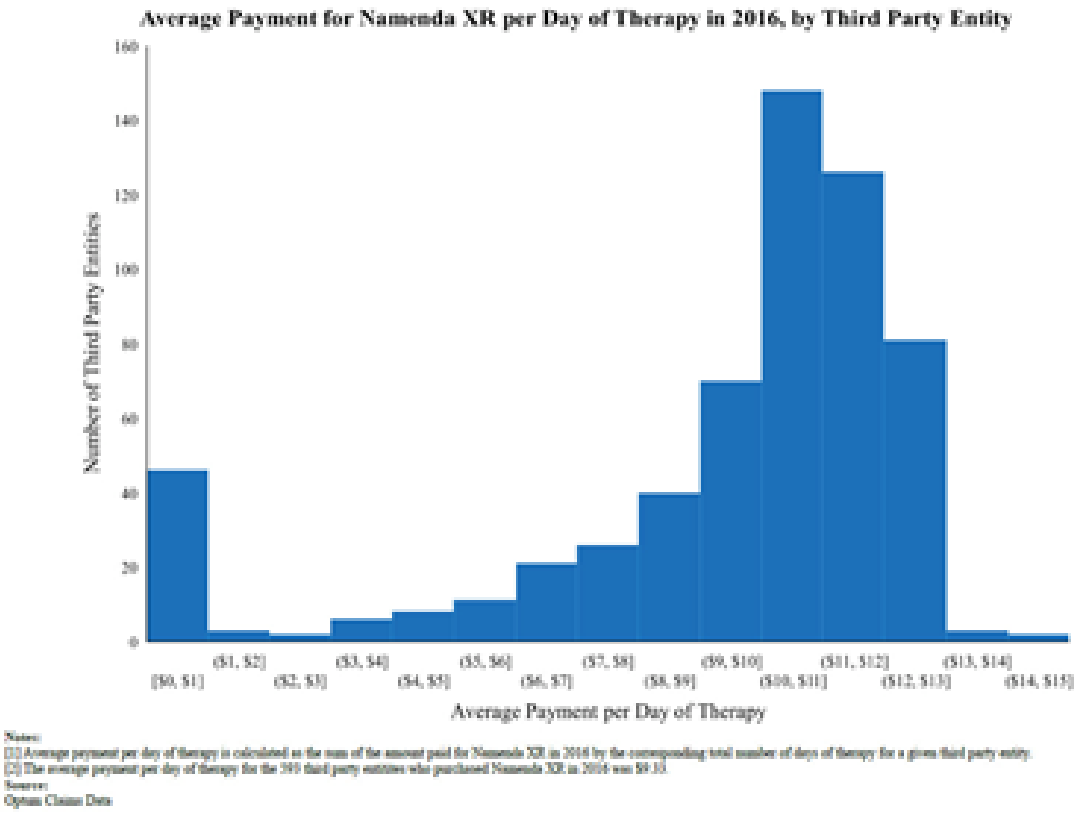
Second, the OptumRx data shows that the actual amounts paid by TPPs (on average) for branded Namenda, *net of rebates*, is still higher than they would otherwise have paid for generics. Below are figures from Lamb's Reply (top: "Figure 2") and Hughes's report (bottom). These two

figures were the ones most discussed by the parties and where the two experts have the most to say about possible overcharges attributable to the pay-for-delay scheme.

Figure 2
Optum Namenda Prices Paid by Third Party Payors



Sources: Hughes Back-up; Optum Data.
Notes: Optum data limited to TPP Class states and exclude Medicaid and CHIP plans.
Average Namenda prices paid by TPPs are calculated net of rebates and exclude patient share of cost.
The Optum rebates per day of therapy are calculated by dividing the rebates specifically paid to Optum by the total days of therapy in the Optum data.



Notes:
[1] Average payment per day of therapy is calculated as the sum of the amount paid for Namenda XR in 2016 by the corresponding total number of days of therapy for a given third party entity.
[2] The average payment per day of therapy for the 593 third party entities who purchased Namenda XR in 2016 was $9.33.
Source:
Optum Claims Data

Lamb's figure shows the prices of all three versions of Namenda paid out by TPPs – and it shows that branded Namenda is more expensive than the generics, even if rebates are factored in. Dr. Lamb calculated these numbers from the Optum data, and he factored in the net rebate numbers calculated by Dr. Hughes, "but limited those rebates to just those paid to Optum." (Lamb Reply at ¶ 46). Thus, unlike Dr. Hughes's estimates of rebates as a percentage of total sales, Dr. Lamb focused solely on the question that Dr. Hughes himself wanted to answer – whether the rebates paid out to Optum actually affected the price of branded Namenda compared to generics. Dr. Lamb's analysis demonstrates that, on average, if TPPs were forced to buy the branded options as opposed to the generic, then they paid more than they otherwise would have, and so were harmed.

Dr. Hughes's analysis, on the other hand, is limited to payments for Namenda XR in 2016. Although the data suggests that some TPPs paid very little for Namenda XR (perhaps because of rebates), that does not mean that the same TPP paid (or would have paid) similarly small amounts

for an IR prescription when compared to a generic. A TPP that was not necessarily harmed by reimbursing for XR (because of the rebates) could still have been harmed by reimbursing for an IR prescription that it was forced to pay for without rebates. That TPP could have also paid reimbursement for generics, which means that it would have also been harmed through generic-generic overcharges. Dr. Hughes provides no indication that his analysis of Namenda XR payments in 2016 is representative of the entire class of plaintiffs and how much they paid for brand and generic memantine (not just for Namenda XR) throughout the class period. Thus, the rebate analysis is insufficient for me to conclude that the average-pricing models Dr. Lamb submits as evidence that is common to the class is incorrect or inapplicable.

Finally, the rebate question overlooks the larger structure of the anticompetitive conduct that SBA alleges. Its theory of injury is not focused solely on the type of brand-generic overcharge just discussed. They also argue that, because generic entry was delayed, it raised generic prices in the actual world compared to the but-for world. Delayed generic entry allegedly resulted in higher generic prices to everyone during the class period, as compared to a scenario in which generic entry occurred earlier. The longer generics are on the market, the cheaper they become. Thus, any TPP that reimbursed for *generics* was harmed – the harm is not restricted only to TPPs that reimbursed for branded Namenda. Forest could not have provided any rebates at all for generics, and so this argument is irrelevant to whether TPPs were harmed by "generic-generic" overcharges. Any TPP that provided reimbursement for higher-priced generics during a period when there would have been more competition in the market but for delayed generic entry was harmed by the pay-for-delay scheme. Put otherwise, with fewer generics on the market due to pay to delay, the price of generics was higher than it would otherwise have been.

Defendants rely largely on the Third Circuit's recent opinion in *In re Lamictal*, 957 F.3d 184, 194 (3d Cir. 2020), which vacated certification of a class after concluding that the district court had failed to give adequate consideration to Defendants' objections to plaintiffs' expert's average-pricing model. But the Third Circuit's misgivings about the average-pricing data in that case stemmed from the district court's assumption that averages were "acceptable" "absent a rigorous analysis" that failed to take the defendants' critiques into account. *Id*. at 194. The district court fundamentally misunderstood defendants' argument that "the prices [of the disputed drug] were never inflated to begin with because [the generic manufacturer of the drug] preemptively lowered its prices before launching," such that it made the average-pricing data unreliable. *Ibid*. Defendants make no such argument in this case; and this court is engaging in precisely the sort of analysis that the Third Circuit found missing in *Lamictal*.

The existence of manufacturer rebates does not necessarily mean that class members were not harmed by an overall decrease in the competitive environment in the market for memantine. Here, given the large differences in price between branded and generic Namenda, the fact that TPPs likely reimbursed for many purchases of memantine, and the fact that one overcharge is sufficient for injury, it seems highly unlikely that there is a sizeable amount of TPPs that were uninjured such that individualized inquiries would predominate over the common ones. Average-pricing data thus serves as common evidence of the injury that plaintiffs could have suffered from having to overpay for memantine.

b. Government Co-Payment

Defendants' second claim is that Lamb's model fails to account for reimbursements that may have been paid by the government. Since Namenda is used to treat Alzheimer's, a large majority of patients would likely have had a portion of their prescriptions paid for through

Medicare Part D plans – TPP-administered prescription drug benefit plans available to Medicare beneficiaries. Hughes estimates that in 2017, almost three in four Americans sixty-five and older were covered by a Medicare Part D plan. (Hughes Report at ¶ 70).

A Medicare Part D plan generally includes four coverage phases: (1) the deductible phase, (2) the initial coverage phase, (3) the coverage gap or "donut hole" phase, and (4) the catastrophic phase. Insured individuals proceed through these coverage phases sequentially. Hughes argues that increased government co-payment and additional manufacturer discounts during the coverage gap and catastrophic phases likely renders some TPPs injured.

During the coverage gap phase, the cost split for generic and branded drugs differ. For generics, the cost is split between the TPP and the patient-beneficiary; but for branded drugs, the cost is split between the TPP, the patient, *and* the brand-name manufacturer, who is legally mandated to provide for a portion of the cost through discounts. A TPP's percentage share of the cost of a branded drug is therefore lower than the percentage that it pays for a generic during this phase, meaning that the actual amount it paid for a branded drug could also be lower than what it would otherwise pay for a generic. The TPP's share portion is similarly low during the catastrophic phase of coverage. The federal government pays upwards for 80% of the cost of all prescriptions during the catastrophic phase, and the TPP and the beneficiary split the remaining 20%. (*Id*. at ¶¶ 72–73). Hughes concludes that average-pricing data is an unreliable metric for injury given the manufacturer discounts and government cost-sharing during these phases of Medicare Part D coverage.

However, Defendants overlook the fact that, before Medicare Part D patients are eligible for the discounts and co-pays in the coverage gap and catastrophic phases of their plan, they must go through the initial coverage phase, during which drug costs are split 75%-25% between the TPP

and the patient. Since there are no discounts or government co-pays during this period, average-pricing data serves as a reliable baseline gauge for what TPPs had to pay. If there were overcharges, TPPs would have suffered that injury during their patients' initial coverage phase of their plan. Dr. Vogt estimates that at least 57.3% of memantine patients covered by Medicare Part D purchased their prescriptions during the initial coverage phase of their plan, during which there would have been no government rebates or subsidies available to the TPP. (Vogt Report at Table 4). One overcharge is sufficient to demonstrate antitrust injury. *See In re Nexium*, 777 F.3d at 27.

Moreover, as was the case with the rebate argument, heavy focus on government copayments within Medicare Part D plans overlooks the fact that SBA alleges harm from generic-generic overcharge. Even if there were a small number of TPPs that – after accounting for all rebates and government co-payment – paid less for a branded Namenda prescription than for a generic, that TPP would still have been harmed if it reimbursed for a generic memantine prescription that would have been cheaper in the but-for world. Dr. Hughes's analysis is unpersuasive insofar as it attempts to compare the prices of branded Namenda with that of generics in the actual world. The correct comparison is "whether a particular plaintiff would have paid more in the but-for world," *Cordes*, 502 F.3d at 108. Antitrust injury can be demonstrated through the use of a "single formula" to calculate but-for fees as long as that method is common to all class members and makes "a valid comparison between the but-for fee and the actual fee paid." *Id*. at 107. Dr. Lamb's average-pricing data, supplemented by Dr. Vogt's estimate of the but-for price attributable to the delayed entry, serves as just such a metric in assessing class-wide injury.

c. Brand Loyalists

Defendants next contend that SBA inadequately accounts for the existence of "brand loyalists" – individual consumers of Namenda who never purchased a generic, even after they

became available. TPPs that reimbursed only for brand loyalist purchases would not have been harmed by Defendants' actions, because the loyalists would have continued purchasing Namenda-branded products regardless of the price difference between Namenda and its generics.

Several district courts have excluded brand loyalists from proposed consumer classes. *See, e.g., In re Flonase Antitrust Litig.*, 284 F.R.D. at 231–32; *see also In re Thalomid and Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 6573118, at *12 (D.N.J. Oct. 30, 2018). Dr. Hughes estimates that approximately 14% to 18% of individual consumers of Namenda met the brand loyalist criteria, in that they did not purchase a generic after they became available. (*Id*. at ¶¶ 25, 108–09).

In arguing that the presence of brand loyalists undermines predominance, Defendants rely heavily on an opinion from the First Circuit, *In re Asacol Antitrust Litig.*, 907 F.3d 42 (1st Cir. 2018), which held that certification of a class with a sizeable proportion of brand loyalists (upwards of 10%) was improper, given the need to identify and remove the uninjured plaintiffs from the class. Certifying a class that included such a high proportion of uninjured plaintiffs would give "defendants no meaningful opportunity to contest whether an individual would have, in fact, purchased a generic drug had one been available." *Id*. at 53.[3]

The plaintiffs in *Asacol* were also indirect purchasers of a drug who, like SBA does here, used average-pricing data to demonstrate antitrust injury. *Id*. at 45. The district court held that the predominance requirement was met and certified the class despite finding "that approximately ten percent of the class had not suffered any injury attributable to defendants' allegedly anticompetitive behavior" because they were brand loyalists. *Ibid*. The First Circuit reversed, holding that this percentage was too high a number for defendants to be able to adequately

[3] In this case, as in *Asacol*, this issue arises in connection with the predominance inquiry, rather than the ascertainability inquiry, though it obviously pertains to both.

"challenge . . . a plaintiff's ability to prove an element of liability." *Id*. at 53. This implicated the defendants' Seventh Amendment rights, as it might have hindered their ability to contest all necessary elements or to present all valid defenses.

However, the existence of individual brand loyalists does not preclude certification of a pay-for-delay class consisting of TPPs only. This situation is unlike the one in *Asacol*, in which the class included "individual consumers who purchased the relevant" products. *Id.* at 46. Here, SBA seeks only to certify a class of TPPs – entities that reimbursed many different consumers. Even if some percentage of individual *patients* are brand loyal – and some undoubtedly are – any one TPP would have suffered an antitrust injury as long as it provided reimbursement for just one overcharged transaction of Namenda or a generic alternative to someone who was not brand loyal. Put differently, the fact that 14-18% of patients would have remained loyal to Namenda (assuming for purposes of argument that to be true) does not mean that 14-18% of the members of the class (TPPs) suffered no antitrust injury. The record contains no estimate of the number of TPPs who reimbursed only "brand loyalists" and thus suffered no antitrust injury; in fact, the record contains no suggestion that any TPPs reimbursed only brand loyal patients. Two factors in the record suggest that, if there were any, the number would be vanishingly small.

First, per Dr. Hughes, the Optum data revealed that 50% of individual consumers filed fewer than six claims for memantine during the class period, and around 17% filed only one claim. (*Id*. at ¶ 117) This suggests that TPPs do not necessarily reimburse for many "repeat clients" over a long period of time – which is understandable for an Alzheimer's drug. Significant consumer turnover mitigates the effect of brand loyalists on TPPs, since it means that TPPs service a more varied clientele when it comes to memantine, and that even brand loyalists do not use the drug for very long. Since one overcharge is sufficient for injury, having many different clients increases

the likelihood that a TPP reimbursed for a non-brand-loyal consumer. "[A]n insurer with brand-loyal members is only uninjured here if every one of its members would have been brand-loyal for all [Namenda] purchases in each 'but-for' scenario." *In re Solodyn*, 2017 WL 4621777, at *18.

Since there was massive switching from brand to generics following generic launch (86.9% market share by 2 months), any TPP that reimbursed for Namenda before generic entry has a very high likelihood of having reimbursed for a patient who would have switched earlier had generics been available, and so would have suffered antitrust injury.

Second, the period of possible "brand loyalty" is not long in relation to the class period. The class period spans from June 2012 to December 2017, and generics only entered the market in July 2015. Thus, reimbursement for confirmed brand loyalists could have only occurred during less than half of the entire class period.

In short, there is no reason to conflate uninjured brand loyal *patients* with the *TPPs* that reimbursed them when analyzing antitrust injury in the context of the pay-for-delay scheme. Dr. Hughes does not identify the number of TPPs that meet the two criteria just discussed, and it appears highly unlikely that any TPP that reimbursed for multiple memantine prescriptions would have only brand loyalists among its insureds. An expert in another indirect-purchaser case opined that the likelihood that a third-party payor with ten independent claims for the drug Niaspan had no generic claims is "approximately 1 in 1 billion" and that, "Even if a TPP reimbursed only three beneficiaries, it would remain unlikely that all the TPP's reimbursements were for brand loyalists." *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678, 717 (E.D. Pa. 2020); *see also In re Restasis*, 335 F.R.D. at 23; *In re Loestrin 24 FE Antitrust Litig.*, 410 F. Supp. 3d at 402. In this case, the Optum data revealed that at least 92% of TPPs reimbursed for more than one prescription of brand Namenda, and that percentage is likely to be higher if reimbursements for generic memantine are

factored in. (*Id*. at ¶ 220). Given the confluence of all of these factors, it seems highly unlikely that the number of TPPs uninjured by the pay-for-delay scheme would be anything other than *de minimis*.

The *Asacol* court noted that it was "not a case in which a very small absolute number of class members might be picked off in a manageable, individualized process at or before trial." *Asacol*, 907 F. 3d at 53. By contrast, I conclude that the number of TPPs that suffered no antitrust injury from the pay-for-delay scheme because they only reimbursed brand loyalists is almost certainly *de minimis*, and perhaps non-existent. Therefore, *Asacol* is not persuasive precedent.

"District courts in this and other Circuits have held that a class may be certified so long as a '*de minimis*' number of class members were uninjured or, conversely, 'virtually all' class members were injured." *In re Restasis*, 335 F.R.D. at 17 (citing cases). The number of uninjured class members to qualify as *de minimis* has not been definitively established, but "one court recently 'suggest[ed] that 5% to 6% constitutes the outer limits of a *de minimis* number of uninjured class members.'" *Ibid*. (quoting *In re Rail Freight*, 292 F. Supp. 3d 14, 137 (D.D.C. 2017)). On this record, Defendants have not demonstrated that the percentage of TPPs that suffered no injury due to the brand loyalty of non-class member patients even approaches that number.

In short, "the fact that some putative class members may be uninjured does not automatically defeat predominance." *Dial Corp*., 314 F.R.D. at 114–15; *see also B & R Supermarkets*, 2021 WL 234550, at *28. Although certain TPPs may be entitled to more recovery than others, that does not mean that individualized issues predominate as to antitrust injury. Defendants have not persuaded me that even a sizeable minority of TPPs would have been uninjured by the pay-for-delay scheme.

d. Additional Arguments

Defendants advance two additional arguments against predominance, neither of which is persuasive.

Defendants argue that generic-only purchasers (and the TPPs that reimbursed for them) are not harmed because individual patients generally pay a flat co-pay, such that any price fluctuations in the generic-only market would not impact their out of pocket situation. Insofar as this argument addresses injury suffered by individual consumers, it can be ignored because they have been dropped from the proposed class definition. And insofar as it addresses injury suffered by TPPs, it is just plain wrong. TPPs do not reimburse consumers for copays; they reimburse PBMs and pharmacies for the difference between the co-pay and the full cost of the drug. TPPs are, therefore, sensitive to price fluctuations in any market for memantine.

Finally, Defendants claim that TPPs were not injured because they probably passed any overcharges to their insureds. But this is sheer speculation on Defendants' part; they offer no evidence that this was the case with memantine. Nor is there evidence in the record tending to show that TPPs calculate additional premiums to impose on patients by factoring in antitrust overcharges or the price fluctuations of a specific drug. *See In re Lidoderm*, 2017 WL 679367, at *23.

A TPP is harmed if it is pays more at any point due to Defendants' misconduct. The fact that it may have later set off that loss by passing the overcharge to its customers – although Defendants have offered no evidence of that here – does not mean that common issues of injury do not predominate the class.

3. Antitrust Damages

SBA proffers an estimate of the total damages suffered by the entire TPP class attributable to the pay-for-delay scheme to meet this element. In this case, "aggregate class-wide damages

equal the difference between the costs paid by class members for [brand Namenda IR and XR] in the actual world versus the costs class members would have paid for [generic Namenda IR] in the 'but-for' world" had there been no pay-for-delay. *In re Restasis*, 335 F.R.D. at 30 (quoting *In re Flonase*, 284 F.R.D. at 232)).

Dr. Vogt describes two types of overcharges attributable to the pay-for-delay scheme. Brand-generic overcharges occur when patients who would have otherwise consumed generic memantine are instead forced to consume branded Namenda IR because generic entry was delayed. These patients – and the TPPs that reimburse them for their purchases – "pay the price difference between Namenda IR and its generic equivalent times the volume of brand Namenda IR consumed which would have been replaced by generic memantine in the but-for world." (Vogt Report at ¶ 54). Generic-generic overcharges occur when the delayed generic entry causes generic prices to be higher in the actual world than the but-for world due to delayed competition. The longer generics are on the market, the cheaper they generally become. Delaying generic entry thus deprives consumers of the additional time that generic manufacturers spend competing with each other. Thus, the overpayment "is the volume of generic drug consumed times the price difference of generics between the actual and but-for worlds." (*Id*. at ¶ 55.).

I conclude that Dr. Vogt has elucidated a methodology that "roughly reflects" the damages incurred by the class of TPPs, and that is attributable to the pay-for-delay theory. *Seijas*, 606 F.3d at 58. He first considered the prices of branded Namenda and generic Namenda in the actual world. Generic Namenda IR entered the market in July 2015 at an average retail price per DOT of $7.79.[4]

[4] Vogt obtained his actual-world prices from IQVIA, a health care data company which provides market data that tracks prescriptions sold measured in dollars and units. More specifically, the numbers were obtained from National Sales Perspectives data and National Prescription Audit data, which each project "100% coverage of the retail and non-retail channels for national pharmaceutical sales." (Vogt Report at ¶ 80). These sources were the same as those used by Dr. Lamb for his antitrust injury analysis.

(*Id.* at ¶ 89). At the time, brand Namenda IR was selling at an average price of $12.32 per DOT. Vogt used these prices – and the price action of generic Namenda over time – to calculate but-for prices based on an earlier generic entry date. For example, the price of generics "fell rapidly" after entering the market, so that one year after entry, the average price of a Namenda generic was $5.56 per DOT and $5.40 two years after DOT. "Thus, by two years after generic entry, the retail price of generic memantine fell to about 44% of what the branded price had been at generic entry." (*Ibid.*). Vogt used these estimates to calculate the but-for price of generic Namenda had generics entered the market in November 2012, when Namenda IR prices were hovering at around $8.91 per DOT. He estimates that the but-for price of memantine (across all forms) had it entered the market at that time would have been around $8.36, and that it would have experienced a similarly quick decline in price as it had experienced in the real world. (*Id.* at ¶ 151). Dr. Vogt then used the differentials between the but-for and actual prices of branded Namenda and generic Namenda to calculate the overcharges attributable – in total – to the reverse-payment strategy.

Dr. Vogt's methodology is "especially appropriate here, where it is impossible to measure the true harm caused by" Defendants' alleged anticompetitive conduct because of the "inherent difficulty of identifying a but-for world." *In re Restasis*, 335 F.R.D. at 32 (internal quotation marks and citation omitted). A plaintiff's "burden of proving antitrust damages is not as rigorous as in other types of cases" because of inherent "limitations" involved in "establishing what the market price of the commodity or service would have been in an unmanipulated market." *New York v. Julius Nasso Concrete Corp.*, 202 F.3d 82, 88 (2d Cir. 2000).

Although courts must carefully evaluate estimates to ensure that the expert's "methodology is a just and reasonable inference" and not speculative, *Comcast*, 569 U.S. at 32, "damages need not usually be demonstrated with precision." *Hickory Secs. Ltd.*, 493 F. App'x at 159 (citation

omitted). Even if individualized inquiries will be required when damages are finally assessed (either following trial or settlement), that "is not sufficient to defeat class certification." *Roach*, 778 F.3d at 405 (quoting *Seijas*, 606 F.3d at 58).

Here, Dr. Vogt's methodology and estimates are clearly sufficient to "roughly reflect" the level of damages incurred by the proposed class.

Defendants claim that SBA's damages estimate runs afoul of *Comcast*, but this is simply not true. *Comcast* merely required that a plaintiff's estimate of damages reasonably correspond to the theories of liability they advance. SBA has done just that, here. It advanced two theories of liability – the hard switch and the pay-for-delay – and they estimated the damages associated with each theory independently. The estimate of damages attributable to pay-for-delay was in no way "contaminated" by the estimate of damages attributable to the hard switch. Nor did *Comcast* "hold that a class cannot be certified under Rule 23(b)(3) simply because damages cannot be measured on a classwide basis." *Id*. at 407. Here, SBA has done exactly what *Comcast* requires by offering proof a measurable estimate of class-wide damages attributable to the pay-for-delay theory.

To the extent Defendants are arguing that *Comcast* overturned the "'well-established' rule in the this Circuit that 'the fact that damages may have to be ascertained on an individual basis is not sufficient to defeat class certification' under Rule 23(b)(3)," *Roach*, 778 F.3d at 405 (quoting *Seijas*, 606 F.3d at 58), they are wrong. Significantly, all of the arguments propounded by Defendants relate to the calculation of the damages that would be owed to any particular TPP. As long as *Roach* is good law in this Circuit, those arguments do not defeat predominance. The predominance requirement is satisfied as to SBA's pay-for-delay theory of liability.

B. **Hard Switch**

1. Antitrust Violation

In prior proceedings related to this litigation, the Second Circuit held that Forest's "hard switch" was anticompetitive, and Defendants are estopped from arguing that it was not. *See Namenda IV*, 2017 WL 4358244, at *11.

Common evidence will be used to prove the existence of the hard switch strategy. For example, as I stated in the decision certifying a direct-purchaser class, to establish the hard switch claim, class members will need to offer, *inter alia* "evidence of pre-announcement communications" about the launch of Namenda XR. *Namenda V*, 331 F. Supp. 3d at 215. Although the class's claims arise out of the antitrust laws of multiple states and not the federal antitrust statutes, as was alleged by the direct purchasers, the question of a legal violation "focus[es] exclusively on [Defendants'] actions and will not vary among class members." *In re Restasis*, 335 F.R.D. at 14. Moreover, as will be discussed below, *see* Section III.D.1.*iii*, *infra*, the various state antitrust laws are for the most part modeled on, and do not vary significantly from, corresponding federal law. Any proof of the hard switch's being an antitrust violation thus centers solely on Defendants' conduct, and no putative class member would need evidence different from any other class member to demonstrate that Defendants' actions violated the antitrust laws. Thus, the hard switch would violate the antitrust laws such that the first element of an antitrust claim is satisfied.

2. Antitrust Injury

The inquiry into whether there is common evidence of antitrust injury for the hard switch class is a different and far more complex matter.

SBA's theory of injury is that, but for the hard switch, TPPs would have been reimbursing for more generic prescriptions; but that because of the announcement of the "hard switch," they ended up reimbursing for Namenda XR prescriptions, which cost a great deal more than a generic

would have. This, SBA alleges, is because a large number of memantine consumers switched quickly to the XR version as a result of the illegally anticompetitive hard switch announcement.

Dr. Lamb analyzed a counterfactual world in which Forest neither announced its intention to discontinue Namenda IR nor took steps to effectuate that plan. He concluded that, but-for Defendants' conduct, "there would have been significantly fewer Namenda XR prescriptions and, at the time of generic Namenda IR entry, significantly more branded Namenda IR prescriptions" such that generics "would quickly take over." (Lamb Report at ¶ 15). By "shrinking [the] base" of IR prescriptions, Forest shifted the memantine market more towards Namenda XR such that TPPs reimbursed for the more expensive drug (which could not be automatically substituted for generics under state drug-substitution laws) rather than the cheaper generic. TPPs were thus overcharged by paying for a larger amount of the more expensive Namenda XR prescriptions that – in the but-for world – would likely have been for generic Namenda.

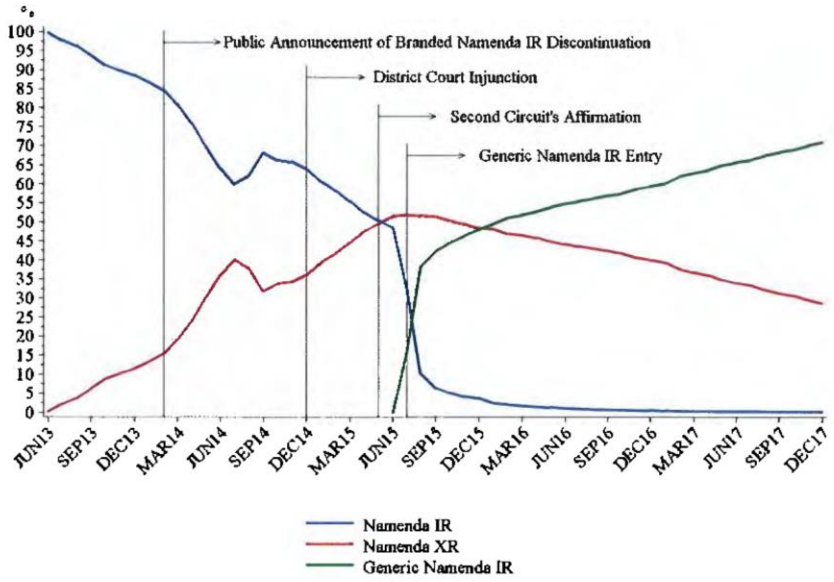
As noted, Namenda XR entered the market on June 13, 2013 and, for some time thereafter, Forest attempted to encourage Namenda IR consumers to switch to the XR version voluntarily, by pulling advertising for Namenda IR, and by urging doctors to prescribe the new XR version. *See Namenda II*, 787 F.3d at 648. However, Forest's internal estimates (which SBA agrees with) projected that only around 30% of Namenda IR users would choose to switch to Namenda XR through its "soft switch" strategy. (Vogt Report at ¶ 133). Forest internal documents reveal that company executives decided to implement the hard switch once they realized that its attempt to get consumers to switch from IR to XR voluntarily was not working well.

On February 14, 2014, Forest announced its plan to discontinue sales of Namenda IR altogether by August 15, 2014 – almost a year before the scheduled generic launch. Without Namenda IR, consumers of memantine were effectively forced to switch to Namenda XR. Forest

estimated that the hard switch strategy would effectively transition approximately 80% to 100% of IR patients to XR. *Id*. at 655. Since IR generics were not bioequivalent to XR, whatever switching to generics that would have occurred after generic market entry would have been slowed significantly. *See id*. at 649. And since consumers very rarely "reverse commute" back to the generic version of a drug they had used before after they have been prescribed a new brand name drug, Dr. Lamb asserts that the hard switch would have made it much more difficult for IR generics to obtain a meaningful market share. (*Id*. at ¶ 116).

Lamb's analysis of the National Prescription Audit data showed that, at the time of the February 2014 "hard switch" announcement, Namenda IR had approximately 85% of the memantine market, while XR had 15%. (*Id*. at Figure 6). But by the time Judge Sweet enjoined the "hard switch" as anticompetitive in December 2014, IR market share was at 65% versus 35% for XR. And when generics entered the market in July 2015 (effectively plummeting IR off the "patent cliff"), IR and XR market share were both around 50%. Thus, Dr. Lamb estimates that upwards of 50% of Namenda patients converted due to the hard switch strategy.

Figure 6
Namenda IR, Namenda XR, and Generic Namenda IR Market Shares



Source: IQVIA NPA Data.

Obviously, that number is significantly higher than the 30% that Forest thought would make the switch under a soft-switch strategy. (*Id*. at ¶ 108).

SBA alleges that this additional shift of patients to XR meant that fewer patients were inclined to convert to competing generics. Had only 30% of Namenda IR users switched to XR, the "base" of IR prescriptions would have been larger, and Lamb posits that the majority of those users would have switched to generic IR – as demonstrated by the fact that, within two months of generic entry, 86.9% of IR users converted. However, because many patients shifted to XR in response to the hard switch, TPP class members were harmed by paying more in reimbursement "for the Namenda XR [patients] purchased than they otherwise would have." (*Id*. at ¶ 109). Put simply, TPPs were overcharged for Namenda XR because "instead of [reimbursing for] generic Namenda IR at low prices, they were forced to buy Namenda XR at higher prices." (*Ibid*.).

3. Individualized Issues Predominate as to the Hard Switch Theory

SBA's theory of injury is perfectly plausible – indeed, in some ways it is much easier to understand than the theory propounded for the pay-for-delay scheme. But SBA has not demonstrated that all (or even most) members of the class for which they seek certification suffered the harm alleged by the hard switch theory. Figuring out which proposed class members in fact suffered the alleged antitrust injury would require an individualized inquiry, which would predominate over the relatively straightforward evidence needed to establish the antitrust violation.

We start with the fact that SBA is seeking to certify what is, by its own admission, an overbroad class. SBA and Dr. Lamb acknowledge that "any meaningful analysis of antitrust injury resulting from the Hard Switch would be limited to those TPP Class members who purchased *at least Namenda XR*." (Lamb Rebuttal at ¶ 155) (emphasis added). This is because the harm from the hard switch was a "forced conversion" of memantine prescriptions to Namenda XR that would otherwise have been for generic memantine. Thus, a TPP could have only paid for an overcharge attributable to the hard switch if (1) the TPP reimbursed for a Namenda XR prescription (2) that would otherwise have been a generic. A TPP could not have been harmed by the hard switch if it never reimbursed anyone for Namenda XR; nor could it have been harmed if the only Namenda XR prescriptions for which it paid were for insureds who would have converted to the branded XR regardless of the hard switch.

This concession by SBA automatically defeats certification of the proposed class, which is defined as "*All* third-party payors indirectly purchased, and/or paid, and/or provided reimbursement for, some or all of the purchase price for branded Namenda IR 5 or 10 mg tablets, their AB-rated generic equivalents, and/or Namenda XR capsules." (ECF 489). That proposed class includes TPPs that did not reimburse any insureds for Namenda XR. In fact, the proposed class consists mostly of TPPs that did not suffer this form of antitrust injury. Defendants provide

evidence that a majority of TPPs that fall within that definition never actually reimbursed an insured for *any* Namenda XR prescription. Defendants' expert, Dr. James W. Hughes's analysis of the Optum data revealed that, out of the 1,659 third-party entities[5] that reimbursed for memantine during the class period, 1,227 of them – around 74% – did not provide any reimbursement for a Namenda XR prescription during the months between the hard switch announcement and Judge Sweet's injunction against the hard switch. (February 2014 to December 2014). (Hughes Report at ¶ 138). More striking is the fact that 1,012 of those entities – around 61% – never provided *any* reimbursement for a Namenda XR prescription at all during the proposed class period, which runs from June 1, 2012 to December 31, 2017. (*Ibid*.).

Dr. Lamb never contends that Dr. Hughes's analysis of the OptumRx data with respect to the proportion of TPPs that reimbursed for Namenda XR is inaccurate; and he acknowledges that the data represents approximately 27% of the total Namenda prescriptions that were issued during the class period. (Lamb Reply at ¶ 33). This is enough for me to conclude that the TPP claims contained within it are representative of the wider class. The data before me shows that at least 61% of SBA's current proposed class definition could not have suffered any antitrust injury from the hard switch because they never reimbursed for Namenda XR.

In light of this data, Defendants argue persuasively that it is impossible to conclude that there is common evidence of injury across *all* (or at least all but a *de minimis* number) putative class members that can be attributed to the hard switch.

Of course, the fact that the proposed class cannot be certified does not mean that a smaller class consisting of only TPPs that reimbursed for Namenda XR could not be certified. *See* Fed. R.

[5] 1,659 entities filed claims for memantine, but not all of them were necessarily TPP class members. This is because some TPPs hire third-party administrators ("TPAs") to file insurance claims on their behalf, and the TPA would be the entity that shows up in the OptumRx data, because it would be the one directly interacting with OptumRx. TPAs do not provide reimbursement and so do not qualify as class members.

Civ. P. 23(b)(c)(4), (5). Courts can and often do certify subclasses – or exclude from a class proposed members who did not suffer injury – in circumstances like this. *See, eg., In re Flonase Antitrust Litig.*, 284 F.R.D. 207 (E.D. Pa. 2012); *In re Wellbutrin XL Antitrust Litig.*, 282 F.R.D. 126, 142 (E.D. Pa. 2011). A limited subclass would be appropriate if there were evidence showing that the hard switch harmed all (or nearly all) Namenda XR reimbursors.

However, certifying a subclass of TPPs that reimbursed for Namenda XR would be inappropriate in this case, because it is far from guaranteed that all (or even most) of the TPPs that made such reimbursement did so as a result of the hard switch.

For the hard switch to have injured a TPP, that TPP must have reimbursed for Namenda XR, and the XR reimbursement must have been for a prescription *that would otherwise have been a generic but for the hard switch.* TPPs that reimbursed for XR prescriptions that would have been XR regardless of whether or not there had been a hard switch would be uninjured by that reimbursement. The NPA data shows that 15% of all Namenda users were already using XR at the time of the hard switch announcement (8 months after the XR launch) – reimbursement to those insureds obviously worked no antitrust injury to any TPP. (Lamb Report at Figure 6). The parties also agree that, had there been no hard switch announcement, 30% of Namenda users would have voluntarily made the switch to the longer-acting XR formulation. (Vogt Report at ¶ 133). None of those reimbursements worked any antitrust injury, either. In other words, the data show, and the parties agree, that many memantine users who switched from IR to XR did so because of consumer (or physician) preferences wholly unrelated to the hard switch announcement. Determining which TPPs reimbursed for prescriptions of XR that occurred only because of the hard switch would require a level of individualized inquiry into patient/physician preferences that would overwhelm the common inquiry.

The data shows that, at the time of generic entry, 50% of memantine users (all of whom were Namenda users) were XR users. SBA's argument presumes that all (or nearly all) of those "additional" switchers did so because of the hard switch. But there is no evidentiary basis for this assumption. There is no reason to assume that some of those patients (or their doctors) would not have decided to prefer XR to a generic because, for example, it only needed to be taken once a day, due to its long-acting properties. Defendants also cite the fact that XR enjoyed a better formulary placement starting in January 2014, which effectively guaranteed that Medicare Part D patients would not have to fight for reimbursement of the branded drug, as often happens once a generic hits the market. (Hughes Report at ¶¶ 142–44). Patients could thus have had reasons to remain with the branded drug, rather than switching to a generic form of Namenda IR, that were entirely unrelated to the hard switch. Determining which TPPs reimbursed for which type of patients would require a highly individualized level of inquiry such that individual issues would predominate over common ones.

SBA does not provide a persuasive estimate for what percentage of Namenda XR's increased market share after the hard switch announcement is actually attributable to that announcement. Dr. Lamb's analysis of the NPA data demonstrates only that Namenda XR gained market share following the announcement. (Lamb Report at Figure 6). But the NPA data shows that Namenda XR was *already* gaining market share at a high rate before the hard switch announcement, and the conversion continued at a similar rate after the announcement. (*Ibid*.). The market share data also demonstrates that XR's market share fluctuated quite significantly in the time between the hard switch announcement and the entry of the preliminary injunction. It is thus far from apparent that all of the additional conversions to XR after the hard switch announcement were attributable to the hard switch.

For example, an analysis of Medicaid data performed by Dr. Hughes showed that, of the individual patients who purchased Namenda XR between its launch and generic entry (i.e., from June 2013 to July 2015), 46% "did not take Namenda XR after generic Namenda IR launched" in July 2015. (Hughes Report at ¶ 127). TPPs reimbursing those patients were not harmed by those XR reimbursements because the patients never purchased Namenda XR *after* generic entry and so were not "forced" to take an XR prescription that otherwise would have been a generic.

The Medicaid data also showed that, of all patients who initiated XR prescriptions between February 1, 2014 and December 31, 2014 (roughly the time between the hard switch announcement and the injunction), 58% of them "subsequently switched to Namenda IR or to an alternative Alzheimer's disease therapy [i.e., to something other than memantine] prior to generic entry." (*Id*. at ¶ 128). And of the cohort that switched to a different treatment, "56% of those patients then subsequently *switched back to Namenda XR within the class period*." (*Ibid*.) (emphasis added). The fluidity in the prescription of Alzheimer's drugs makes it impossible to conclude that the hard switch, as opposed to some other factor or factors, occasioned the switching. The individualized inquiry that would be needed to tease out which switchers were attributable to the hard switch fails to meet the predominance requirement for certification.

All this shows that simply reimbursing an insured for XR does not automatically admit of the inference that the hard switch was the reason for the patient's use of XR. As such, one cannot presume that the hard switch harmed all (or even most) TPPs that reimbursed for XR.

Of course, Defendants raised the same (or an analogous) argument in opposing certification of the pay-for-delay theory, so the question naturally arises as to why the Court found that argument persuasive in one case and not in the other. The answer lies in the nature of the evidence provided by SBA in support of certification under each theory. While the evidence suggested that

the number of TPPs who suffered no antitrust injury from pay-for-delay (i.e., the number of TPPs who did not reimburse a single insured who would not have converted to a generic) was *de minimis*, I cannot reach that same conclusion on the basis of the evidence relating to the hard switch. In the pay-for-delay context, there was strong evidence, from market-level data, that 86.9% of Namenda IR prescriptions switched to generic Namenda *within two months after generic entry*. There is no dispute that branded Namenda IR and IR generics are effectively perfect substitutes in the memantine market. Thus, the extremely high conversion rate as soon as generics hit the market allows one to infer, simply from the rapidity with which patients made the switch upon generic entry, that an overwhelming percentage of *all IR prescriptions* would have gone generic had the opportunity to do so occurred earlier. Had there been earlier generic entry, a TPP that reimbursed for multiple memantine purchases during the class period would have almost certainly incurred at least some form of overcharge from the pay-for-delay scheme – whether that be brand-generic or generic-generic.

But as the above analysis demonstrates, there is no data relating to the hard switch that is similarly persuasive, or that admits of an inference that all those who made the switch from IR to XR after the hard switch announcement did so because of the hard switch announcement.

This is not like the direct-purchaser action, in which a general citation to market demand suffices to prove common injury. In the direct-purchaser action, putative class members were wholesalers who bought memantine directly from manufacturers. Thus, evidence of market shifts for Namenda (i.e., 50% IR-to-XR conversion versus 30% in the but-for world) was adequate evidence of class-wide injury, because a generic-only wholesaler would have been harmed if the hard switch caused it to purchase fewer generics (and thus make less money from selling generics) than it otherwise would have but-for Defendants' conduct. If the hard switch depleted the market

share of Namenda IR, it depleted the market share for generic-only wholesalers as well. Decreased demand for IR generics thus harmed even generic-only wholesalers by "suppressing generic sales and their attendant savings." *Namenda V*, 331 F. Supp. 3d at 209.

The same principle does not hold for indirect purchasers. Evidence of an improperly enlarged market for Namenda XR has no bearing unless a TPP participated in that market. Dr. Hughes has presented unrebutted evidence that most TPPs did not. And even if a TPP reimbursed for XR, the above discussion demonstrates that it is not guaranteed that it would have been due to the hard switch. Therefore, ascertaining whether a TPP class member was affected by the hard switch would require a predominantly individualized inquiry.

Ultimately, the reason why I am certifying a pay for delay class but declining to certify a hard switch class is because SBA has not shown that only a *de minimis* number of TPPs that could be members of a possible hard switch subclass would be uninjured. This contrasts with the pay-for-delay scheme, where the court was able to – on the basis of the evidence presented – find it extremely unlikely that more than a *de minimis* number of TPPs suffered no antitrust injury.

I thus decline to certify either the proposed hard switch class or any subclass that might be able to be carved out of it.

iii. Impact of State-Law Claims on Class Action

SBA alleges antitrust monopolization and restraint-of-trade claims arising under the laws of 24 states and the District of Columbia. It also brings claims arising under the consumer-protection laws of 14 states. (Second Amended Complaint, ECF 326).[6] Although the state statutes are similar, they are not identical. Defendants claim SBA offers "no administrable way to try these

[6] SBA brings state, rather than federal, claims because "Under the United States Supreme Court's decision in *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 745-46 (1977), indirect purchasers of products sold at supra-competitive prices lack standing to sue under federal antitrust statutes" but "may still bring suit under state antitrust laws, if a state permits such claims." *Namenda VI*, 2018 WL 7197233, at *1.

claims without individual issues predominating," because the variations in state laws contain idiosyncrasies that affect the elements of each claim and the damages that will be available. (ECF 465 at p. 35).

They cite indirect-purchaser cases that have held that because class actions brought under the laws of various states require that "claims must be adjudicated under the law of so many jurisdictions, a single nationwide class is not manageable." *In re Bridgestone/Firestone Tires Prods. Liab. Litig.*, 288 F.3d 1012, 1018 (7th Cir. 2002); *see also In re Niaspan*, 464 F. Supp. 3d at 725 (requiring plaintiffs to submit "charts identifying the substantive elements of each state law claim, an analysis of all variations between the state law claims, and a proposed trial plan through which these variations may be manageably addressed"). Defendants argue that the variations in the state laws precludes not only a finding of predominance, but that it also precludes a finding of commonality and typicality.

Whether the existence of state-law claims precludes certification is no different from the rest of the predominance inquiry. A plaintiff must demonstrate that "any variations in relevant state laws do not predominate over the similarities." *Langan v. Johnson & Johnson Consumer Companies, Inc.*, 897 F.3d 88, 97 (2d Cir. 2018). In answering this question, "district courts must do more than take the plaintiff's word that no material differences exist." *Ibid*. Instead, they must "undertake a considered analysis of the differences in state laws," and whether any significant variations may precipitate the "potential need for subclasses." *Id*. at 98.

For example, in *Langan*, the Second Circuit vacated the certification of a class alleging violations of the consumer-protection laws of eighteen states because "the district court's analysis consisted of one paragraph," which "did not sufficiently engage with" the defendants' arguments. *Id*. at 98.

Ultimately, however, "Variations in state laws do not necessarily prevent a class from satisfying the predominance requirement." *Id.* at 97. Many indirect-purchaser classes have been certified even though they were brought under the laws of different states. *See, e.g.*, *In re Restasis*, 335 F.R.D. at 33–39 (more than 30 states); *In re Loestrin 24 FE Antitrust Litig.*, 410 F. Supp. 3d at 352 (29 states); *In re Lidoderm*, 2017 WL 679367, at * 27 (17 states). This follows the Supreme Court's dicta that "Predominance is a test readily met in certain cases alleging . . . violations of the antitrust laws." *Amchem Prods*., 521 U.S. at 625. What is ultimately important is that the state laws do not "var[y] widely on [ ] critical issues" such that the elements of the claim or the burdens of proof required are different. *Id*. at 609–10.

A. State Antitrust Claims

SBA's Second Amended Complaint alleges state monopolization (Count One) and restraint-of-trade claims (Count Two). Defendants do not articulate any specific differences between the antitrust laws of the various states, and an analysis of the statutes reveal no significant variations that preclude a finding of predominance.

As to the monopolization claims, almost all of the state statutes contain language that is substantially similar to that of the federal Sherman Act, which states that no entity "shall monopolize" or "attempt to monopolize." 15 U.S.C. § 2. Nine of the statutes have language that is *identical* to that of the Sherman Act. *See, e.g.*, Fl. Rev. Stat. Ann. § 542.19 (noting it is unlawful for any entity to "monopolize" or "attempt to monopolize"); Haw. Rev. Stat. Ann. § 480-9 (same); Me. Rev. Stat. tit. 10, § 1102 (same); Neb. Rev. Stat. Ann. § 59-802 (same); N.M. Stat. Ann. § 57-1-2 (same); N.C. Gen. Stat. Ann. § 75-2-1 (same); Or. Rev. Stat. Ann. § 646.730 (same); Wis. Stat. Ann. § 133.03(2) (same); D.C. Code Ann. § 28-4503 (same).

Many of the other statutes contain language that is effectively the same, prohibiting the "establishment, maintenance, or use of a monopoly." *See, e.g.*, Ariz. Rev. Stat. Ann. § 44-1403;

Mich. Comp. Laws Ann. § 445.773 (same); N.D. Cent. Code Ann. § 51-08.1-03 (same); R.I. Gen. Laws Ann. § 6-36-5 (same); W. Va. Code Ann. § 47-18-4 (same); *see also* Iowa Code Ann. § 553.5 ("A person shall not attempt to establish or establish, maintain or use a monopoly"); Minn. Stat. Ann. § 325D.52 (prohibiting "The establishment, maintenance, or use of . . . monopoly power"); Nev. Rev. Stat. Ann. § 598A.060(1)(e) (prohibiting "Monopolization of trade or commerce"); S.D. Codified Laws § 37-1-3.2 (prohibiting "monopolization . . . or an attempt to monopolize").

The same situation exists for the state analogs to Sherman § 1's prohibition against conspiracies "in restraint of trade or commerce." 15 U.S.C. § 1. *See, e.g.,* Ariz. Rev. Stat. Ann. § 44-1402 (prohibiting a "conspiracy . . . in restraint of . . . trade or commerce"); N.D. Cent. Code § 51-08.1-02 (same); W.Va. Code Ann. § 47-18-3(a) (same); 740 Ill. Comp. Stat. Ann. 10/3(2) (prohibiting "conspiracy" that "unreasonably restrain[s] trade or commerce"); Nev. Rev. Stat. Ann. § 598A.060(1)(e) (prohibiting "conspiring to monopolize trade or commerce").

Most critically, even the states that have statutes that do not closely track the language of the Sherman Act have effectively harmonized their antitrust statutes with that of the federal law such that the elements needed to sustain a monopolization or restraint-of-trade claim – at the most basic level – are effectively the same under the state and federal laws.

Fundamentally, "The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). For a restraint-of-trade claim under Sherman § 1, "a plaintiff must prove two elements: '(1) a combination or some form of concerted action between at least two legally distinct

economic entities that (2) unreasonably restraints trade.'" *Freeland v. AT&T Corp.*, 238 F.R.D. 130, 153 (S.D.N.Y. 2006) (quoting *Geneva Pharm. Tech. Corp. v. Barr Lab. Inc.*, 386 F.3d 485, 506 (2d Cir. 2004)).

There is no indication that any state's antitrust laws require proof of elements different from those that must be proved under the Sherman Act with respect to monopolization or restraint-of-trade claims. For example, although New York's version of the Sherman Act – the Donnelly Act – does not contain express language prohibiting monopolization, courts have interpreted the statute to "require identical basic elements of proof" as the Sherman Act. *Reading Intern., Inc. v. Oaktree Capital Mgmt. LLC*, 317 F. Supp. 2d 301, 332-33 (S.D.N.Y. 2003) (quoting *Altman v. Bayer Corp.*, 125 F. Supp.2d 666, 672 (S.D.N.Y. 2000)). The same is true of California's Cartwright Act. Although California courts have cautioned that interpretations of the Sherman Act are merely "instructive" as to the Cartwright Act, both statutes, at bottom, "carry forward" the understanding that "unreasonable restraints of trade are prohibited." *In re Cipro Cases I & II*, 61 Cal. 4th 116, 142 (Cal. 2015) (citation omitted). State courts in Tennessee – another state that does not have a statute containing language identical to that of the Sherman Act – have held that "the enforcement of the state antitrust laws should be consistent with the federal laws." *Freeman Indus. LLC v. Eastman Chem. Co.*, 172 S.W.3d 512, 521 (Tenn. 2005).

Many of the states even have statutes requiring that their antitrust laws "be construed in harmony with ruling judicial interpretation of federal antitrust law." Kan. Stat. Ann. § 50-163; *see also* Iowa Code Ann. § 553.2 ("This chapter shall be construed to be complement and be harmonized with the applied laws of the United States . . . to achieve uniform application of the state and federal laws prohibiting restraints of economic activity and monopolistic practices."); Neb. Rev. Stat. Ann. § 59-829 (requiring courts to "follow the construction given to the federal

law by the federal courts" when "any provision" of the antitrust law "is the same as or similar to the language of the federal antitrust law").

In sum, the Court does not see any substantive discrepancy between the various state antitrust laws that would preclude this case's going forward as a class action.

So Defendants turn to procedural discrepancies. They argue that the statutes of limitations applicable to the antitrust claims vary between states. But, "Challenges based on the statute of limitations . . . have usually been rejected and will not bar predominance" because it goes "to the right of the class member to recover, in contrast to underlying common issues of the defendant's liability." *In re Linerboard Antitrust Litig.*, 305 F.3d 145, 163 (3d Cir. 2002) (citation omitted). If all or part of the claims of particular members of the certified class are time-barred under relevant state laws, those defenses can and will be raised at a later date. Variations in limitations periods are irrelevant to whether there exist common questions of law or fact that go to the heart of Defendants' potential liability as to the claims alleged.

This case is unlike the *Royal Park* cases – on which Defendants rely – in which the plaintiffs' claims arose out of residential mortgage-backed securities (RMBS) that passed through different owners and assignors, and whose underlying contracts were possibly breached at different times. Although the litigation rights of the putative class were ultimately obtained by one entity, a determination of when each cause of action accrued – and the possible statute-of-limitations defenses available to each – would have involved a "complex analysis" that would have required the district court to "determine the 'residence' of the original assignor" as well as to "identify the owner of the claim at the time *each* [breach creating a cause of action] occurred and trace the assignment of litigation rights since that time," ultimately requiring a "choice-of-law analysis" as to each potential claim. *Royal Park Investments SA/NV v. U.S. Bank Nat'l Assc.*, 14-cv-4394

(AJN), 2018 WL 1750595, at *17 (S.D.N.Y. Apr. 11, 2018). To complicate matters further, some of the contracts were executed abroad, which required the court "to apply the statute of limitations of the 'foreign jurisdiction where a nonresident's cause of action accrued,'" *Royal Park Investments SA/NV v. U.S. Bank Nat'l Assc.*, 324 F. Supp. 3d 387, 399 (S.D.N.Y. 2018) (citation omitted).

No similar difficulties arise in this case. Like other courts, I find that that the statute-of-limitations issues here can be adequately dealt with at the damages stage, as there is a "sufficient constellation of common issues" at the heart of the dispute that "binds class members together" as to the fundamental question of liability. *Waste Mgmt. Holdings, Inc. v. Mowbray*, 208 F.3d 288, 296 (1st Cir. 2000); *see also In re Monumental Life Ins. Co.*, 365 F.3d 408, 421 (5th Cir. 2004). This is not a situation in which class members' causes of actions arose at vastly different points in time. Instead, the focus of the arguments for and in defense of Defendants' liability all pertain to the common factual and legal questions arising from Defendants' actions.

As I stated in an earlier order in these proceedings, "if the [statute-of-limitations] issue is important enough to [Defendants], they can call relevant cases under relevant laws to the court's attention." *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, plc.*, 15-cv-6549 (CM), 2018 WL 7197233, at *20 (S.D.N.Y. Dec. 26, 2018). Defendants have done little more than simply raise the issue that different states may have different statutes of limitations under their antitrust laws. They have not explained why any such differences would make adjudication of SBA's claims overly burdensome, or why these differences would predominate the core antitrust questions that underpin SBA's allegations. This does not preclude a finding of predominance.

B. State Consumer-Protection Claims

SBA also alleges unfair-competition and unjust-enrichment claims arising under the laws of 14 states. Like the antitrust statutes, many of these statutes are worded identically in that they

prohibit "unfair methods of competition." Fla. Stat. Ann. § 501.204(1); *see also* Idaho Code Ann. § 48-603 (same); 815 Ill. Comp. Stat. Ann. 505/2 (same); Mass. Gen. Laws ch. 93A. §2(a) (same); Neb. Rev. Stat. Ann. § 59-1602 (same); N.H. Rev. Stat. Ann. § 358-A:2 (same); N.C. Gen. Stat. Ann. § 75-1.1(a) (same).

The statutes that do not contain the exact "unfair methods of competition" language contain language that is extremely similar, prohibiting "unconscionable" or otherwise "deceptive" or "fraudulent" practices. *See* Ala. Code § 8-19-5(27) (prohibiting "unconscionable, false, misleading, or deceptive act or practice"); Cal. Bus. & Prof. Code § 17200 ("unlawful, unfair or fraudulent business act"); Mich. Comp. Laws. Ann. § 445.903 ("Unfair, unconscionable or deceptive methods"); Mo. Rev. Stat. § 407.020 ("deception, fraud, false pretense . . . unfair practice"); Nev. Rev. Stat. § 598A.0923(3) ("deceptive trade practice"); N.M. Stat. Ann. § 57-12-3 ("Unfair or deceptive trade practices and unconscionable trade practices"); Utah Code Ann. § 13-11-5(1) ("unconscionable act or practice").

Defendants argue that, while these statutes are worded similarly, state courts have interpreted the operative phrases differently such that the tests for whether a defendant is liable of having engaged in an unfair trade practice varies depending on the state. They point out that "unfair" is not necessarily the same as "unconscionable" or "deceptive" and that the use of these terms in different statutes may lead to different standards of proof.

Yet, Defendants do no more than simply point out the existence of these slight discrepancies. They do not identify how SBA's allegations may "fail to satisfy the required elements under the laws of these jurisdictions," *In re Zetia (Ezetimibe) Antitrust Litig.*, 2019 WL 1397228, at *29, or whether they may be cognizable under certain statutes but "not cognizable claims under the consumer protection laws of" others. *Id.* at *31. Although they cite to state court

cases that purportedly demonstrate different "tests" as to what constitutes an unfair practice, Defendants fail to show – in practice – how the statutes would be applied differently in *antitrust cases* like this one. There is no indication whatever that the serious antitrust allegations that SBA advances in this case – if proven – would not be a violation of each of these states' consumer-protection statutes.

Ultimately, any substantive variations that may arise from the discrepancies within these consumer-protection statutes are eliminated by the fact that nearly all of the states in question also have statutes that harmonize state provisions with that of the Federal Trade Commission Act. *See, e.g.,* Ala. Code § 8-19-6 (noting that "due consideration and great weight shall be given where applicable to interpretations . . . relating to Section 5(a)(1) of the Federal Trade Commission Act"); Fla. Stat. Ann. § 501.204(2) (same); Idaho Code Ann. § 48-604 (same); 815 Ill. Comp. Stat. 505/2 (same); Cal. Bus. & Prof. Code § 17001; Mass. Gen. Laws ch. 93A. §2(b) (statute "will be guided by the interpretations" of the FTC Act); 15 Mo. Code. Regs. Ann. Tit. 15 § 60.090 ("An unfair practice is any practice which" offends "the Federal Trade Commission, or its interpretive decisions"); Neb. Rev. Stat. Ann. § 59-829 ("shall follow the construction given to the federal law by the federal courts"); Nev. Rev. Stat. § 598A.0923(3) (a deceptive practice is one that "violates a state or federal statute"); N.H. Rev. Stat. Ann. § 358-A:13 ("guided by the interpretation and construction given Section 5(a)(1) of the Federal Trade Commission Act"); N.M. Stat. Ann. § 57-12-4 ("guided by the interpretations given by the federal trade commission and the federal courts"); Utah Code Ann. § 13-11-2(4); ("not inconsistent with the policies of the Federal Trade Commission Act"). These harmonization provisions are critical because "practices that violate the Sherman Act and other antitrust laws" satisfy the standard of "unfairness" under the FTC Act. *FTC v. Indiana Fed. of Dentists,* 476 U.S. 447, 454 (1986); *see also FTC v. Sperry & Hutchinson Co.,*

405 U.S. 233, 247 (1972) (suggesting that actions that "restrained trade" qualify as "an unfair method of competition and an unfair act and practice in violation of Section 5" of the FTC Act). This means that "state laws with equivalent 'unfairness' language and an FTC Act harmonization provision can safely be assumed to have similarly broad scope." *In re Zetia*, 2019 WL 1397228, at *29. More precisely, any conduct that would qualify as "unfair" under the FTC Act – which violations of the antitrust laws certainly would – would also violate the state provisions at issue. This serves to make it such that any anticompetitive conduct – if proven – would constitute an unfair trade practice such that "proof of anticompetitive conduct [will] establish[ ] a violation of each state's laws." *In re Solodyn*, 2017 WL 4621777, at *20.

The unfair-trade-practices laws in two states (Michigan, North Carolina) do not contain explicit harmonization provisions. But Defendants have not cited a single case demonstrating that these consumer-protection statutes are applied by their respective states in ways that would lead to a substantive difference with the laws of the rest of the states. Indeed, North Carolina courts interpret their statute "in light of the principles" of those advanced by the FTC Act and the "spirit of the antitrust laws." *Johnson v. Phoenix Mut. Life Ins. Co.*, 300 N.C. 247, 265 (N.C. 1980) *abrogated on other grounds by Myers & Chapman, Inc. v. Thomas G. Evans, Inc.*, 323 N.C. 559, 569 (N.C. 1988). And the case that Defendants cite for the proposition that Michigan's consumer-protection act is interpreted differently from the FTC Act – *In re Motor Vehicles Canadian Exp. Antitrust Litig.*, 350 F. Supp. 2d 160, 189 (D. Me. 2004) – is not a Michigan state court case at all, but a case from the federal district court in Maine. That Maine court did not cite a single Michigan case that held that the Michigan statute should be interpreted differently from the FTC Act. Nor did it discuss antitrust liability.

In the end, the acts underpinning SBA's claims all arise from the allegedly anticompetitive conduct of the hard switch and reverse payments. It appears, from this court's review of these fourteen laws, that a violation of each state's antitrust laws would run afoul of that state's consumer-protection laws as well. Fundamentally, the legal issues of liability, and the factual issues pertinent to that determination, are common to all class members.

In accordance with the above discussion, the predominance requirement of Rule 23(b)(3) is met.

2. Superiority

The last step of a certification analysis is the superiority requirement of Rule 23(b)(3), which requires that a court find that "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Rule 23(b)(3) provides four factors for determining whether a class action is superior to other methods for plaintiffs' pursuit of their claims:

> (A) the class members' interests in individually controlling the prosecution or defense of separate actions;
>
> (B) the extent and nature of any litigation concerning the controversy already begun by or against class members;
>
> (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and
>
> (D) the likely difficulties in managing a class action.

Rule 23(b)(3)(A) – (D).

Here, all of these factors favor certification.

Prospective class members have expressed no interest in prosecuting separate actions. The Court is also unaware of any litigation currently ongoing involving the same class members. Similar to the direct-purchaser action, "several considerations weigh in favor of concentrating the litigation in this particular forum." *Namenda V*, 331 F. Supp. 3d at 220. As I noted in that case, I

have been deciding dispositive rulings in this case since September 2015, and the "parties have thus already litigated several issues that would surely arise in any new case." *Ibid*. This consideration has only grown since that decision.

Finally, whatever difficulties in managing this class action are dwarfed by the extraordinary difficulty (if not practical impossibility) of bringing the likely thousands of individual cases against Defendants if a class were not certified. Like the direct-purchaser action, this action provides the perfect example for class treatment because it may "facilitate the redress of claims where the costs of bringing individual actions outweigh the expected recovery." *In re U.S. Foodservice Inc. Pricing Litig*., 729 F.3d at 130.

Defendants argue that the differences in state law preclude a finding of superiority, as individual actions would better address the varying statutes. However, as just discussed, that argument does not preclude certification. Ultimately, this indirect-purchaser action does not present any unique challenges as others that have been similarly certified. *See, e.g.*, *In re Restasis*, 335 F.R.D. at 39.

The superiority requirement of Rule 23(b)(3) is met.

Arbitration Argument

Defendants make one final argument: they insist that class certification would be improper because Forest's rebate contracts with potential TPP class members (which contain various terms) *may* contain mandatory arbitration provisions such that they would preclude litigation. They claim that, if these TPPs are certified as class members, Forest would lose its right to arbitrate any of the individual disputes. They insist that SBA should be obliged to provide a full list of potential class members so that Forest can determine which entities may need to arbitrate.

It bears noting that this argument is largely hypothetical. Forest has not demonstrated that most TPP class members would be contractually required to arbitrate the claims in suit. As SBA notes, Forest is in the best position to provide the court with the identities of the potential TPP class members that have agreed to arbitrate the claims in this lawsuit. After all, Forest has the contracts that supposedly undergird the argument that Forest has raised. In the absence of strong evidence indicating that this is an issue relevant to most TPPs, or that it is an issue that otherwise predominates the common issues of the class, I am constrained to conclude that it does not preclude certification.

CONCLUSION

For the foregoing reasons, SBA's motion for class certification is granted in part and denied in part in accordance with the limits established by this opinion.

The Court certifies the following class with respect to SBA's pay-for-delay theory of liability only:

> All Third-Party Payors who indirectly purchased, and/or paid, and/or provided reimbursement for, some or all of the purchase price for branded Namenda IR 5 or 10 mg tablets, their AB-rated generic equivalents, and/or Namenda XR capsules, other than for resale in Alabama, Arizona, California, D.C., Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island (for purchases after July 15, 2013), South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin, for consumption by themselves, or their members, employees, insureds, participants, or beneficiaries, from June 1, 2012 through December 31, 2017.

Although SBA has not included the pro forma class exclusion of all judges and the chambers staff of those judges assigned to work on this case in their amended class definition, I will exclude them. Thus:

> Excluded from the proposed Class are: (a) Defendants and Defendants' parents, subsidiaries and affiliates; (b) fully-insured health care plans (i.e., health plans that purchased insurance from another third-party payor covering 100% of the insureds'

prescription drug benefits on behalf of the Plan's members and beneficiaries); (c) all federal or state governmental entities, excluding cities, towns or municipalities with self-funded prescription drug plans; (d) Pharmacy Benefit Managers ("PBMs"); and (e) all judges presiding in this case, their chambers staff, and any members of their immediate families, and all counsel of record.

The Clerk of Court is respectfully directed to close Dkt. Nos. 444 and 551.

It is so ordered.

Dated: February 11, 2021

Chief Judge

BY ECF TO ALL COUNSEL